POLICY & REGULATION
Brexit considerations, p. 14

COMMERCIAL
Edwards "Harpoons" another mitral-valve catch, p. 9

R&D
Spotlight on Thync, making neuromodulation for psoriasis, p.11

Medtech Insight
Issue 74
medtech.pharmaintelligence.informa.com

Pharma Intelligence Informa

December 18, 2017

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MTI 100: Medtronic Still Leads, While M&A, Strategic Moves Elevate Others

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Medtronic PLC has held strong to its leadership position in the global medtech industry for the second consecutive year, having raked in the most revenue from medical device sales in its most recently completed fiscal year.

The multinational easily knocked the once-reigning medtech champion **Johnson & Johnson** off its throne in last year's MTI 100 after J&J pared down its medical device division significantly just as Medtronic was bulking up with its $43bn acquisition of Covidien. *(Also see "MTI 100: The Rise And Fall Of Medtech's Giants" - Medtech Insight, 16 Dec, 2016.)*. The 2017 edition of MTI 100 – *Medtech Insight*'s roll call of the top 100 companies ranked according to their medical device- and diagnostics-related sales for their most recent completed fiscal year – show that the distance between Medtronic and J&J has grown even wider (See full MTI 100 rankings on pp. 12-13). Medtronic's revenue for fiscal 2017 (it's most recent fiscal year, which ended on May 31) increased 3% from the previous year to $29.71bn. J&J's medical device-related revenue, meanwhile, stayed virtually flat at $25.12bn.

And while some might think that Medtronic might be taking a rest away from the M&A trail after the Covidien merger, the medtech giant has continued to dig into its pockets to broaden its offerings in the past two years. Some of deals were small bolt-ons, but others were meatier transactions, such as its $1.1bn acquisition of **HeartWare International Inc.** and the $350m purchase of gynecological assets from **Smith & Nephew PLC**.

Indeed, Medtronic is proving itself to be a veritable driving force in the growth of the global medtech industry. Of the $166.7bn generated in fiscal 2016/2017 by the ten biggest MTI 100 companies, Medtronic's revenue alone accounted for nearly a fifth of that total.

The top 10 (*See table, p. 5*) of the MTI 100 highlights some companies that have climbed up the ranking through astute M&A moves and well-executed growth strategies.

One example is **Philips Healthcare**, which has succeeded in jumping up the most places and overtaking long-time imaging rivals **GE Healthcare** and **Siemens Healthineers**. Philips had been a diversified corporation similar to GE and Siemens – albeit on a much smaller scale – but its lighting and consumer electronics businesses was putting a drag on its other divisions, including health care. After selling off its consumer electronics business in 2013, Philips announced in September 2014 it was splitting off its lighting business and becoming a focused health-tech company combining its health-care and consumer lifestyle divisions. *(Also see "INTERVIEW: Philips bullish about new HealthTech direction" - Medtech Insight, 12 Mar, 2015.)* The following year was spent executing the reorganization and 2016 was the defining year in which Philips was

CONTINUED ON PAGE 5

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MTI 100

BREXIT

POLICY & REGULATION

CONTINUED FROM PAGE 1

able to fully capitalize on its new structure and sharpened focus. That efforts looks to have helped pull it from the brink and up the MTI 100 rankings.

Stryker Corp. and **Abbott Laboratories Inc..** have also moved up a couple of positions, mainly through M&A. Stryker was the most prolific shopper in 2016, chalking up eight acquisitions in total, two of which were billion-dollar deals - $2.28bn for hospital disposables company Sage and $1.28bn for automated external defibrillator specialist Physio-Control.

2016 was a pivotal year for Abbott too in terms of M&A; it inked two significant deals – the $25bn acquisition of heart-device maker St Jude Medical and the smaller, but later proved to be extremely troublesome, $5.8bn transaction for IVD company Alere. Neither of these deals were closed within 2016 though – Abbott's top-line growth that year was largely organic; but the St Jude Medical purchase was completed in January 2017, which is why St. Jude's 2016 annual report was not available and it has subsequently been left out of this edition of MTI 100. *(Also see "Abbott Becomes CRM Player Overnight By Completing St. Jude Deal" - Medtech Insight, 5 Jan, 2017.)* Although some, including *Medtech Insight*'s predicted that the Alere transaction was going to fall through after doubts were cast over Alere's bookkeeping and business practices, the two companies resolved their differences in April this year to complete the transaction. *(Also see "Despite Legal Dispute, Abbott Set To Buy Alere for $5.3bn" - Medtech Insight, 18 Apr, 2017.)*.

With the addition of these two hefty businesses in 2017, it would be a safe bet that Abbott could find itself even higher up next year's MTI 100 table.

WHAT'S AHEAD

Abbott likely will not be the only firm continuing its ascent up the ranks. **Becton Dickinson & Co.** (up two places from last year to reach now No. 7) made one of 2017's largest acquisition – the $24bn deal for **CR Bard Inc.** to create one of the biggest vascular access company. *(Also see "BD, CR Bard Merger To Create Vascular Access Device Giant" - Medtech Insight, 24 Apr, 2017.)*.

We might also see Mother Nature play a hand – to varying degrees – in companies' review rankings due to hurricanes that hit earlier this year, including September's Hurricane Maria and its devastating impact on Puerto Rico, where many large medtech players have facilities. Companies like Becton Dickinson and **Lantheus Holdings Inc.** have said that it is still hard to quantify in dollar terms just what the impact is of from the storm, while others have put some figures to the damage. Medtronic, for example, has estimated that it is likely to incur costs of $55m to $65m, with the majority of the impact coming from the firm's minimally invasive and restorative therapies groups. *(Also see "Medtronic Lowers Hurricane Maria Cost Estimates" - Medtech Insight, 9 Nov, 2017.)*.

Also, several firms will be dropping out of next year's MTI 100 as they get acquired and absorbed. These include image-guided interventional therapy specialist **Spectranetics Corp.**, which will enter the folds of Philips, and home-hemodialysis specialist **NxStage Medical Inc.**, which has been acquired by **Fresenius Medical Care AG & Co. KGAA**.

Also of note is the rise of medtech players from China. As *Medtech Insight* expands its geographic coverage, this 2017 edition of MTI 100 includes four

CLICK
The MTI 100 and rankings for the top 10 IVD, Cardiology, Orthopedics and Imaging companies can be found online at http://bit.ly/2Bf6EKz

MTI 100: Top 10 Medtech Companies

RANKING 2017	RANKING 2016	MOVEMENT FROM PREVIOUS YEAR	COMPANY	FISCAL 2016* TOTAL MEDTECH SALES (US$ MILLION)	FISCAL 2015* TOTAL MEDTECH SALES (US$ MILLION)
1	1	Same	Medtronic	29710.00	28833.00
2	2	Same	Johnson & Johnson	25119.00	25137.00
3	6	Up 3	Philips Healthcare	19278.49	19413.60
4	3	Down 1	GE Healthcare	18291.00	17639.00
5	4	Down 1	Siemens Healthineers	15258.36	15020.18
6	5	Down 1	Cardinal Health	13524.00	12430.00
7	9	Up 2	Becton Dickinson	12483.00	10282.00
8	7	Down 1	Roche Diagnostics	11648.04	11255.57
9	10	Up 1	Stryker	11325.00	9946.00
10	11	Up 1	Abbott Laboratories	10095.00	9710.00

**Fiscals 2016 and 2015 for most companies*
Source: MTI 100 company league tables (2017)

new Chinese entries – **Shinva Medical Instruments** (No. 47), **Jiangsu Yuyue Medical Equipment** (No. 78), **MicroPort Scientific Corp.** (No. 80) and **Lepu Medical Technology (Beijing) Co. Ltd.** (No. 85). These are cash-rich, growing companies that are looking to expand beyond their domestic markets, so it is worth watching out for them. MicroPort Scientific, for one, earlier this year acquired **LivaNova PLC**'s cardiac rhythm management business, which generates about $250m in sales per year. This should greatly boost MicroPort's top-line and its position in next year's MTI 100. *(Also see "China's MicroPort Bags A Bargain In LivaNova's CRM Unit" - Medtech Insight, 21 Nov, 2017.)*

Go to pp 12-13 for the full MTI 100 ranking for 2017.

Published on 12/08/17

VC Deals Analysis: Could 2017 Smash $6bn Barrier?

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This year could set a five-year record for the most venture capital and private-equity dollars raised by emerging medtech companies, even smashing through the $6bn barrier for the first time, after November recorded several hefty fundraisings.

Of the 19 medtech VC financing deals recorded by *Medtech Insight*'s VC deals tracker, the 17 that disclosed financial details raised an impressive $622.1m. The shortfall from the very modest deal volume – 10 less than the month before and three less than in November last year – was mitigated by the significant deal value coming from the month's top five transactions that raised $50m and over. (See Figure 1.)

November's rich pickings have boosted total deal value this year to date to $5.90bn, just over $100m – a very feasible target to hit for December – to exceed $6bn and break the five-year record. (See Figure 2.). Looking at the deal value, month-by-month over the last five years, 2017 has proven to be a consistently solid performer. Bar February, where its takings were the lowest compared to the same month in the previous years, there were five months – January, March, May, September and November – where 2017 outshone every year back to 2013.

CONSUMER GENOMICS RISING STAR

November's top-five companies in financing totals came from the two traditionally attractive product/therapy areas of investment – IVD and cardiology. (See Table 1.)

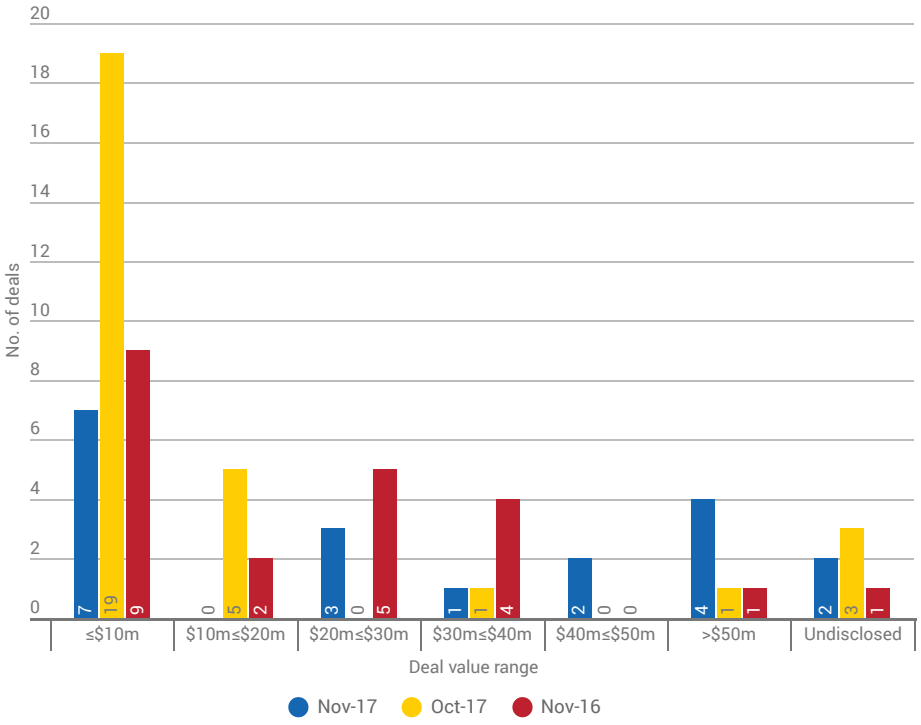
Although a mere fraction of the $900m series B funds raised by Grail in March, **Progenity Inc.**'s none-too-paltry $125m series B was the biggest round in November. This, and the other two companies in the top three – Annoroad and Counsyl – all target similar markets by offering gene tests and testing services for women's health, reproductive health and cancer management. California-based Progenity, which is focused more on the clinical community, said it will use the funds to further enhance its existing portfolio in these areas, but it is also looking to expand into gastrointestinal health and the new capital will accelerate development of its GI platform of precision molecular diagnostics tools, precision therapeutics, microbiome analytics, and consumer health nutrition.

CLICK
For more details about VC dealsin 2017 and previous years, go to Medtech Insight's VC deals tracker at http://bit.ly/2ztwiLc.

Beijing-based Annoroad – the second largest round with $105m – leverages its proprietary next-generation sequencing platform to offer diagnostic services to the clinical community, and directly to consum-

FIGURE 1

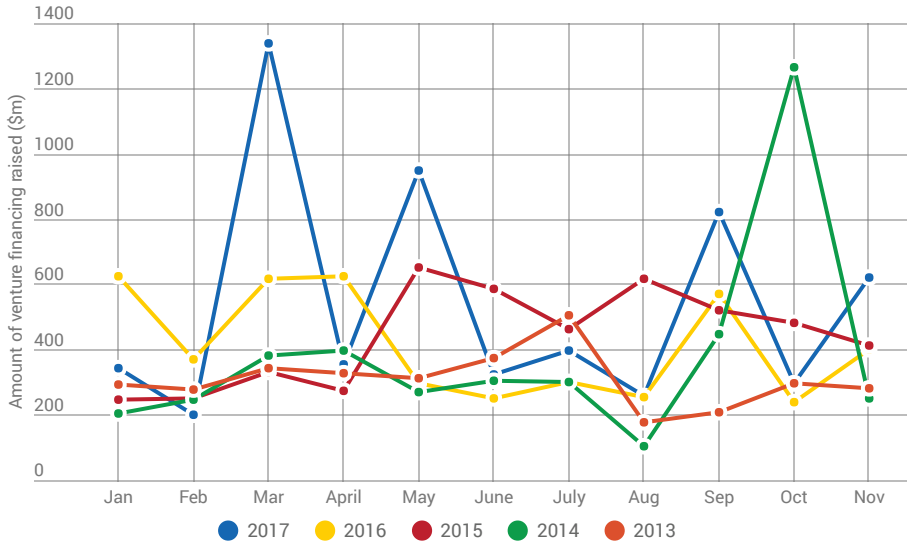
No. Of Deals, By Amount Raised, Nov. 2017 Vs Oct. 2017 Vs Nov. 2016



Source: Medtech Insight VC deals tracker

FIGURE 2

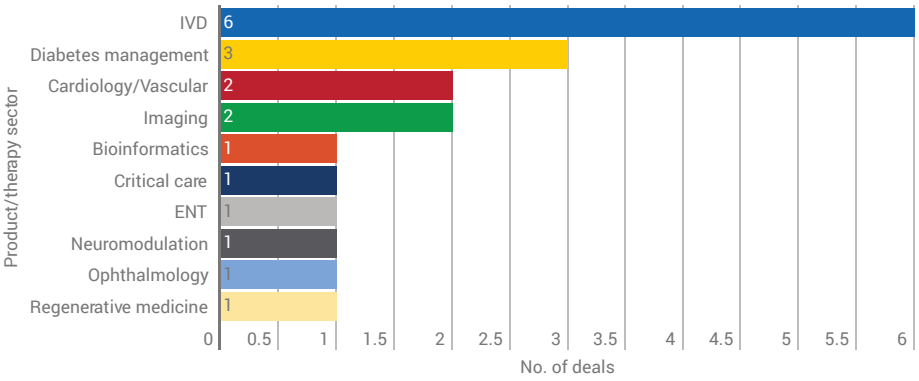
5-Year Trend: Monthly VC Deal Value, January-November, 2013-2017



Source: Medtech Insight VC deals tracker

FIGURE 3

No. Of Deals, By Product/Therapy Areas, November 2017



Source: Medtech Insight VC Deals tracker

ers. The company has a few well-known names from the Chinese health care investment community within its pool of backers, including Ping An Ventures and GTJA Investment Group. Annoroad said it will use the proceeds to scale up its business and accelerate its R&D pipeline among other things. Counsyl, like Ancestry.com, offers its services mainly to consumers and is more focused on prenatal testing, women's health and hereditary disorders.

It may not be surprising to some that the top three deals involved companies that have similar offerings and highlight not only investors' belief in the huge potential of the non-invasive prenatal testing market segment, but also in the consumer genomics marketplace. This point was underscored by Paula Dowdy, **Illumina Inc.**'s senior VP and general manager of commercial operations for EMEA, in an interview with *Medtech Insight* earlier this year. While companies like Ancestry.com and **23andMe Inc.** have met with commercial success in the US, consumer genomics companies like these have yet to really take off in Europe. But the next five years should see things turn around, Dowdy predicted. *(Also see "Illumina Enters Second Wave Of Growth As Genomics Demand Swells" - Medtech Insight, 27 Jul, 2017.)*.

Matching prior months, IVD was the most popular sector in the number of deals in November, but cardiology, usually in the second position, was beaten last month by diabetes management. (See Figure 3.)

Published on 12/11/17

TABLE 1

Top-5 VC Deals, November 2017

RANKING	COMPANY	GEOGRAPHIC BASE	PRODUCT/ THERAPY SECTOR	AMOUNT RAISED	FINANCING ROUND	TOTAL INVESTMENT
1	Progenity	California, US	IVD	$125m	Series B	Undisclosed
2	Annoroad	Beijing, China	IVD	$105m	Undisclosed	Undisclosed
3	Counsyl	California, US	IVD	$80m	Undisclosed	$173m
4	Xeltis	Zurich, Switzerland	Cardiology / Regenerative medicine	€45m ($52m)	Series C	Undisclosed
5	EBR Systems	California, US	Cardiology	$50m	Undisclosed	Undisclosed

*Source: **Medtech Insight**VC deals tracker*

M&A Analysis: M&A Loses Momentum In November

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Following October's extraordinary boom, November suffered a sharp slowdown in medtech M&A deal activity.

Nine deals were recorded on *Medtech Insight*'s M&A Deal Tracker, the lowest volume of the year to date and a steep decline from the 30 deals announced and closed in October. *(Also see "M&A Analysis: October Notches 30 Deals In Big M&A Boom" - Medtech Insight, 12 Nov, 2017.)* It also repeated the low deal count seen in the same period last year. *(Also see "M&A Analysis: November Deal Making Hits Whole New Low" - Medtech Insight, 13 Dec, 2016.)*

Despite M&A losing momentum in the penultimate month of the year, November managed to score a few notable high-value deals. In the biggest value buy of the month,Chinese-owned-**Shanghai Pharmaceuticals Holding Co. Ltd.** agreed to acquire **Cardinal Health China** in a deal worth $1.2bn. The sale includes Cardinal Health's pharmaceutical and medical products distribution business in China but does not include Cardinal Health's remaining businesses in China, including the recently acquired **CordisPatient Recovery** business. The transaction is expected to close by the end of Cardinal Health's fiscal year, subject to closing conditions and regulatory clearances.

"Amid the national health-care reform, the acquisition of the Cardinal Health China business will further strengthen our leadership in the distribution and retail pharmacy network, and expedite our transformation to become a modern global health-care provider," Shanghai Pharma Chairman Zhou Jun said in a statement. "This will also facilitate the growth of our pharmaceutical manufacturing business, enabling us to play a significant role in the Government's 'Healthy China' initiative."

Owens & Minor Inc. announced the acquisition of **Halyard Health Inc.**'s surgical and infection prevention business of for approximately $710m in cash. The division provides health-care supplies and solutions that target the prevention of health-care-associated infections. The addition of Halyard Health will increase scale and profitability across Owens & Minor's global business, while also enhancing the company's product portfolio and expansion into new geographical markets, the company said.

The deal helps Halyard, which spun off from Kimberly-Clark in 2014, focus on their medical devices business, which includes respiratory, digestive, pain-management, and intravenous therapy devices. *(Also see "Kimberly-Clark completes spin-off of Halyard Health" - Medtech Insight, 4 Nov, 2014.)* "This transaction represents a natural evolution and is a milestone moment for both of our businesses," Halyard CEO Joe Wood said in a statement. "It accelerates our transformation to becoming a pure-play medical devices company and provides significant resources to accelerate our growth."

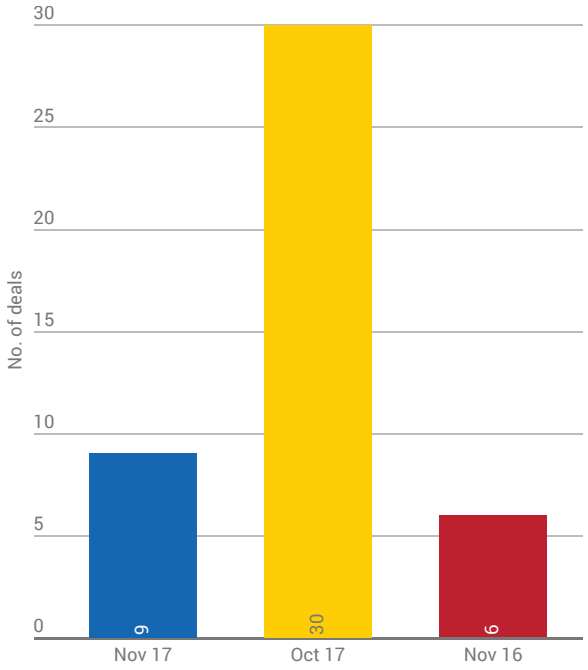
LivaNova PLC struck a deal to sell its cardiac rhythm management business for $190M to Chinese joint-venture partner **MicroPort Scientific Corp.** LivaNova's CRM unit generates sales of around $250m a year *(Also see "China's MicroPort Bags A Bargain In LivaNova's CRM Unit" - Medtech Insight, 21 Nov, 2017.)* and is the smallest of LivaNova's key businesses, the other two being cardiac surgery and neuromodulation. It recorded sales of $249m in 2016, accounting for around 21% of total sales, which came in at $1.2bn. CRM sales declined 4% from 2015, as LivaNova struggled to grow its 2-3% share in a market dominated by much bigger CRM players like Medtronic PLC and Abbott Laboratories Inc. (via its St Jude Medical acquisition) and Boston Scientific.

Merit Medical Systems paid $100m to pick up **Bard, BD's** biopsy assets. Vincent Forlenza, chairman and CEO of BD said the acquisition was a step forward in the regulatory review process of BD's planned acquisition of Bard. "We continue to expect that the BD and Bard transaction will close in the fourth calendar quarter of 2017, subject to customary closing conditions and additional regulatory approvals, including the US Federal Trade Commission and other regulatory bodies," Forlenza said in a statement.

In its eighth acquisition of the year, **Philips** picked up start-up

FIGURE 1

M&A Deal Volume Nov. 17 vs Nov. 16 vs Oct. 17



*Source: **Medtech Insight** M&A Deal Tracker*

Despite M&A losing momentum in the penultimate month of the year, November managed to score a few notable high-value deals.

Analytical Informatics, which was created by researchers at the University of Maryland in Baltimore. The start-up specializes in vendor-agnostic software that provide performance data trend and analysis to hospitals so they can improve the radiology departments' clinical and operational efficiency. Its core technology, *AI Bridge*, is a data aggregation and electronic medical record middleware platform which Philips plans to integrate into its *PerformanceBridge Practice* software. *(Also see "Shopping Spree Not Over For Philips, Bags Data Analytics Start-Up" - Medtech Insight, 24 Nov, 2017.)*

"Integrating Analytical Informatics' software tools and applications into our current offerings will enable us to accelerate the delivery of next-generation technology, software and services, to bring the power of operational intelligence and decision support to radiology," Philips Radiology Solutions general manager Sham Sokka said in a statement. "We'll be in an even stronger position to provide our customers with a host of solutions and help them maximize opportunities to do more with less, while delivering patient-centric care."

Genetic information services company **Invitae Corp.** announced its fourth acquisition of the year. The San Franscisco-based company agreed to buy reproductive and family health genetics company **CombiMatrix Corp** for an undisclosed price. Invitae has made several acquisitions this year, picking up AltaVoice, CancerGene Connect, Good Start Genetics and now CombiMatrix. The deal is set to position Invitae as a leader in family and reproductive health genetic information services, which is the second-leading genetic testing category after cancer.

In other notable deals of the months, **Imagia,** a Montreal-based health-care AI company developing radiomics biomarkers and clinical decision support system acquired medical imaging software firm **Cadens Medical Imaging**.

Welsh medical device company **Flexicare**, announced the acquisition of the Netherlands based **Medisize BV** in a deal that will create a company with an annual turnover of £60m in intensive and emergency care. The current focus of Flexicare is in manufacturing airway management systems for anesthesia, ventilator breathing, resuscitation and breathing management systems primarily in the UK, North America and Japan.

The acquisition of Medisize B.V. for an undisclosed amount will be Flexicare's third and largest acquisition to date. For the year ended Nov 2016 Flexicare recorded sales of £28.5m, and the company is expected to deliver 40% organic growth in 2017 with revenues for November 2017 coming in at over £40m. Whilst the revenues for Medisize are not publicly available, analysts indicate that the acquisition will add an additional £20m of revenues. The acquisition also marks Flexicare's first move into the European markets.

MGC Diagnostics Corporation announced it agreed to be acquired by private equity partner, Altus Capital Partners, Inc. Altus is a private equity firm that makes control investments in middle market manufacturing businesses.

To date, 183 deals have been recorded on *Medtech Insight's* M&A Deal Tracker so far in 2017, putting the year slightly ahead of the 177 deals in 2016 but still far behind the 237 deals carried out in 2015.

Published on 12/11/17

Harpoon Finds Its Whale: Edwards Spends Up To $250m For Beating-Heart Mitral Repair Option

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Harpoon Medical's Minimally Invasive Mitral Valve Surgery System

Photo credit: Harpoon Medical Inc.

Edwards Lifesciences Corp. acquisition of Baltimore-based **Harpoon Medical Inc.** gives Edwards another minimally invasive tool to treat diseased mitral valves and rewards the faith of Epidarex Capital, an early investor in Harpoon Medical, that focuses on early-stage medical technologies in markets overlooked by most other venture capitalists.

Under the terms of the merger agreement announced Dec. 7, Edwards paid $100m in cash for Harpoon at closing on Dec. 1, and has agreed to pay up to $150m more in milestone payments over the next decade. Edwards obtained the option to buy Harpoon as part of an undisclosed investment in Harpoons Series B round of funding in December 2015. *(Also see "Harpoon Medical: Beating-Heart Mitral Valve Repair" - Medtech Insight, 14 Jul, 2015.)*

The *Harpoon* system is a tool that allows for echocardiography-guided, minimally invasive surgical repair of regurgitant mitral valve. Using Harpoon, a surgeon can access the patient's left-ventricle through a small incision and anchor expanded polytetrafluoroethylene sutures running from the valve leaflet to the ventricle wall parallel to the chordae tendineae and then adjust the tension on the sutures to stabilize the prolapsed mitral valve leaflet and restore the valve's coaptation and function, according to Harpoon.

"The benefit of [Harpoon's] technology is to be able to streamline the [mitral] repair procedure for more consistent outcome," Edwards' Corporate VP for Surgical Heart Valve Therapy, Bernard Zovighian said during Edwards investor conference on Dec. 8. "From a patient standpoint, this is a big deal too. Today, open heart surgery is obviously heavy with long recovery time."

Once it reaches the market, the Harpoon system will cost about $20,000 including training surgeons to use it. Zovighian believes the system will be cost-effective at this price because, minimally

invasive surgery reduces downstream costs compared to open-heart surgery. Traditional open mitral valve repair surgery is a complex procedure only performed by a small group of expert surgeons and requires cardiopulmonary bypass, an open sternotomy and a long hospital stay for the patient, he explained. By contrast, the minimally invasive, beating-heart repair procedure does not require bypass and requires only a small incision, so the patient recovery-time is shorter.

Zovighian estimated that that 30,000 of the 110,000 mitral valve surgeries performed annually in the US, Japan, and Europe could be performed with Harpoon. The most similar competitor is **NeoChord Inc.**'s *NeoChord* device, but Harpoon believes their system will be competitive with NeoChord because it is smaller and easier to implant.

The company expects the Harpoon system to earn a CE mark soon to be available commercially in Europe in the second half of 2018. During the first half of 2018, Edwards will build its team in Europe supporting Harpoon and then run training programs to teach surgeons how to use Harpoon before launching it into the market.

Harpoon is part of Edwards' plan to grow its surgical heart valve business 2% to 4% over the next year, Zovighian said. "Our pipeline is very much aligned with patient needs that will remain in surgery. We have the right platform, the right strategy, the right pipeline to deliver true benefit the patient and to have a successful business."

The CE mark is supported by the results of a trial in which echocardiography-guided minimally invasive surgery with the Harpoon system successfully treated severe mitral valve regurgitation in 27 of 30 consecutive patients enrolled in the trial, and 22 of those patients had no more than mild regurgitation six-months later. James Gammie, the surgeon at the University of Maryland School of Medicine that invented the Harpoon system and co-founded the company, presented the results of the trial were presented by Harpoon's at the TCT Conference in Denver and they were simultaneously published by the *Journal of the American College of Cardiology* on Nov. 1

WATCH

Visit our website at http://bit.ly/2C6vj4B to access the video Beating-Heart Mital Valve Surgery With The Harpoon Procedure.

ACQUISITION REWARDS EPIDAREX' EARLY INVESTMENT

Harpoon was started by Gammie and Bill Niland, who met when Gammie performed a successful beating-heart aortic valve repair surgery on Niland's mother in 2010. The two formed Harpoon in 2013 to develop Gammie's invention, the device that would become the Harpoon system.

Epidarex was among Harpoon's first supporters after it was spun-out of the University of Maryland School of Medicine and founded in 2013. Epiderix led the $3.2m Series A funding along with the Maryland Venture Fund and the Abell Foundation. The venture firm was founded in in Bethesda, Maryland and now has eight people and offices in Edinburgh, Scotland, and Tokyo.

Managing partner Kyparissia Sirinakis, based in the Maryland office, told *Medtech Insight* that Harpoon is an example of an early-stage investment that may have been overlooked by other investors because many VCs are reluctant to invest in early-stage medtech right now.

"We are very passionate about this thesis that true early-stage investing in the life-sciences sectors where there are not a lot of investors doing old-fashioned, early-stage investing," she said. "We are company-builders. So we will often take companies out of universities or actually spinning them out of corporations, and also setting-up companies themselves." Epidarex is confident that the Harpoon system can take market-share in the mitral repair surgery segment because it is "a very elegant solution for a real problem and the clinical results have been fantastic," Sirinakis said.

Sirinakis said that Edwards was one of the companies she talked to when Epidarex was first considering investing in Epidarex – "We made sure this was on their map." When the Series B round was coming together, Medtronic and Boston Scientific also showed interest, but Edwards negotiated the best deal for Harpoon, which included an option to acquire it. "We thought it was a really capital-efficient way to get to a potential exit and utilize their money to do the CE mark trial," she explained.

Epidarex was especially well-placed to work with Harpoon early in its development because it maintains so many relationships in the lifesciences community in the mid-Atlantic region, an area that not many VCs are familiar with, compared to, for example, the Massachusetts, Minnesota, or Northern California, Sirinakis said.

"We fundamentally came together to take advantage of what we think is a real opportunity – certainly in this region as well as other areas of the country – where there's really not a lot of venture capital, but a lot of great deals – a lot of fantastic, world-class universities. But there just isn't as many venture capitalists fishing in those areas," she said.

"Maybe it comes from our background, coming out of the angel-investing world, but the ability to go and sit and work with the portfolio companies, because we come in so early, [allows us] to be very hands-on," she said. "Being able to drive the forty minutes to sit with the Harpoon guys, for example, to review things and really be an active member of the team is very important, especially very early in these companies lives. And we think it's important to work closely with the universities and the [local medtech] ecosystem."

"We have so many opportunities to help shape, and give feedback to, the community, which we think is really important, because some of the technologies are world-class." For example, Sirinakis said she first met Gammie before Harpoon was spun-off from the university when she was speaking at small round-table seminar on raising money for start-ups, and he later told her that that seminar helped form Harpoon's early approach to seeking investors. And Epidarex' partners also maintain ongoing relationships with university tech transfer offices "which are often under-resourced."

"We look at medtech in general as under-ventured, because where we play in that early equity-funding gap, its often that you can get the angel investors in, but to get the money to do the early feasibility trials [is difficult]," Sirinakis said. Even in the medtech hotbeds around Minneapolis, Boston, and San Francisco, it is harder for small medtechs to find venture funding

for early stage technologies than it is for early-stage pharmaceutical or biotech companies and even corporate investors are struggling to find co-investors to complete deals for early medtech companies, she said.

"There's a bit of a misperception that the exits are not as large. And there are a lot of risks. There's the regulatory risk on top of the reimbursement risk," she said. "There's also a little bit of a misperception that corporate buyers in the medtech space aren't going to come in very early, they're not going to pay too much, and then you're going to struggle to get reimbursement."

Published on 12/12/17

START-UP SPOTLIGHT:

Thyncing Twice About Psoriasis

CATHERINE LONGWORTH catherine.longworth@informa.com

Silicon Valley startup **Thync**, a bioelectronics company founded in 2016, is exploring using its wearable neuromodulation device to treat the symptoms of psoriasis.

The common, chronic, skin disorder causes patches of skin with silvery scales and red, flaky areas that can be sore, itchy and painful. It currently has no cure and its etiology remains largely a mystery. Current treatment options are based on controlling the symptoms using topical creams, systemic therapies or biologic drugs. Most patients are expected to need lifelong treatment as no therapy can provide a complete cure of psoriasis. According to the World Health Organization, the prevalence of psoriasis in countries ranges between 0.09% and 11.43%, making psoriasis a serious global problem with at least 100 million individuals affected worldwide.

"We first used our technology to help people lower stress and anxiety," Thync CEO, Isy Goldwasser told *Medtech Insight*. "We developed a way to stimulate nerves on the back of the neck to create this systemic effect across your body which lowers stress and anxiety. We built the entire technology into a product which we brought to the consumer market initially and by doing that we got a lot of feedback. Some of that feedback said that we could take this technology further and now we're directing it towards a very different area which is psoriasis."

Thync's device works by placing the neuromodulation device onto a set of gel pads containing electrodes, which are placed on the base of the neck. The device is then linked to a smartphone app which holds a number of neurostimulation programs which can be played for 10 to 15 minutes. The electrodes deliver level electrical pulses to stimulate the nerves in the neck that connect to regions of the brain.

Photo credit:Thync

The US start-up reported positive results from a pilot study evaluating the use of its neuromodulation technology to treat psoriasis.

THYNC INC
Los Gatos, California

Contact: Isy Goldwasser

Industry Segment: Bioelectronics

Business: Wearable neuromodulation devices

Founded: 2016 (as a health-care business)

Founders: Isy Goldwasser, Sumon Pal, and Anil Thakur

Investors: Noosphere Ventures, Khosla Ventures

Board of Directors: Isy Goldwasser, Sumon Pal

"The way the technology works is by targeting spinal nerves between C3 and T1 at the base of the neck and these are sympathetic ganglia that are important in upstream of the bodies sympathetic response," Thync's Chief Scientific Officer Sumon Pal explained. "By lowering sympathetic activity which is involved in the fight or flight response, we aim to lower stress or anxiety but this sympathetic nervous system also plays an important role in immune responses and by altering the immune response, that is how we can treat psoriasis."

The Thync team were inspired to explore the technology to treat psoriasis after receiving unexpected feedback from a customer using their neurostimulation device. "One of our early customers for our anxiety and stress product was a psoriasis patient who let us know that his psoriasis had cleared completely after using our technology for about one month," Goldwasser said.

"That's when we began to understand that in addition to stress and anxiety which are things you usually associate with your nervous system, there is this whole other range of conditions that are accessible by treating the nervous system," Goldwasser said. "We made a discovery that being able to modulate the nervous system was linked to the body's immune response and that link once we understood that that means we can help people with these auto immune disorders. The reason psoriasis is special is because it it's on the skin, you can see it, there's a visual read out and you can see when someone is getting better right away which is extremely helpful."

The company believes the technology

CONTINUED ON PAGE 22

MTI 100: Medtech Insight's Top 100 Companies 2016/2015

RANKING	COMPANY	FISCAL 2016 TOTAL MEDTECH SALES (US$ MILLION)	FISCAL 2015 TOTAL MEDTECH SALES (US$ MILLION)
1	Medtronic[1]	29710.00	28833.00
2	Johnson & Johnson[2]	25119.00	25137.00
3	Philips Healthcare[3]	19278.49	19413.60
4	GE Healthcare	18291.00	17639.00
5	Siemens Healthineers[4]	15258.36	15020.18
6	Cardinal Health[5]	13524.00	12430.00
7	Becton Dickinson[6]	12483.00	10282.00
8	Roche Diagnostics[7]	11648.04	11255.57
9	Stryker	11325.00	9946.00
10	Abbott Laboratories[8]	10095.00	9710.00
11	Boston Scientific	8386.00	7477.00
12	Danaher[9]	7823.70	7569.30
13	Zimmer Biomet	7684.00	5998.00
14	Baxter International[10]	7476.00	7218.00
15	B Braun	7160.55	6802.42
16	Alcon Laboratories	5812.00	1099.00
17	3M[11]	5527.00	5420.00
18	Olympus[12]	5302.54	5031.56
19	Terumo[13]	4739.05	4338.29
20	Smith & Nephew	4669.00	4634.00
21	Grifols	4481.35	4366.34
22	Fujifilm[14]	3994.33	3580.90
23	Dentsply Sirona[15]	3745.30	2674.30
24	CR Bard[16]	3714.00	3416.00
25	Getinge Group	3479.90	3585.15
26	Fresenius Medical Care[17]	3392.00	3346.00
27	Thermo Fisher[18]	3339.20	3243.90
28	Hologic Inc[19]	3058.80	2832.70
29	Edwards Lifesciences	2963.70	2493.70
30	Intuitive Surgical	2704.40	2384.40
31	Shimadzu[20]	2522.77	2256.56
32	Alere[21]	2364.37	2438.64
33	Sysmex[22]	2302.41	2087.23
34	Coloplast[23]	2181.90	2069.34
35	ResMed[24]	2066.00	1838.00
36	Miraca[25]	1882.53	1749.63
37	Teleflex Medical	1868	1809.7
38	bioMerieux[26]	1856.70	1722.19
39	Drager[27]	1822.95	1885.21
40	Convatec	1688.30	1650.40
41	Halyard Health	1592.30	1574.40
42	Nihon Kohden[28]	1532.65	1367.71
43	Valeant Pharmaceuticals	1518.00	1495.00
44	Integer*[29]	1386.80	800.40
45	Qiagen	1337.99	1280.99
46	Bio-Rad[30]	1320.00	1310.00
47	Smiths Medical	1289.25	1335.91
48	Shinva Medical Instrument	1259.06	1202.17
49	Elekta[31]	1251.81	1330.54
50	LivaNova[32]	1213.93	1204.60

[1]FY2017 vs FY2016 (year ends Apr. 30)
[2]Medical Devices business only
[3]Healthcare units only, excludes Lighting.
[4]Fiscal 2017 vs fiscal 2016
[5]FY2017 vs FY 2016 (year ends June 30). Medical segment only.
[6]Year ends Sep 30 2016
[7]Diagnostics division only.
[8]Diagnostics + Vascular + Other
[9]Diagnostics + Dental only
[10]Renal + Fluid Sys + Surgical Care only.
[11]Healthcare
[12]FY2017 vs FY2016 (year ends Mar. 31). Medical business only.
[13]Fiscal 2016 ends Mar 31, 2017
[14]FY2017 vs FY 2016 (year ends Mar. 31).Information Solutions - Healthcare only.
[15]Completed merger with Sirona Feb 2016.
[16]Signed M&A deal with BD in 2017
[17]Dialysis Products only. Excludes Health Care Services.
[18]Specialty diagnostics only
[19]FY2017 vs FY2016 (year ends Sept. 30)
[20]Analytical & Measuring instruments + Medical Instruments only
[21]FY2015 = restated. Products + Services
[22]FY2017 vs FY2016 (year ends Mar. 31)
[23]Year ends Sept 30.
[24]FY2017 vs FY2016 (year ends June 30)
[25]FY 2017 vs FY2016 (year ends Mar. 31)
[26]Clinical applications only. 2015 biotheranostics sales excluded
[27]Medical business only.
[28]Year ends Mar. 31.
[29]Formerly Greatbatch. Renamed Integer after merger with Lake Region Medical end of 2015. Medical sales only.
[30]Clinical Diagnostics segment.
[31]FY2017 vs FY2016 (year ends June 30)
[32]2016 was first full year as a public company, adjusted 2015 results accordingly.

RANKING	COMPANY	FISCAL 2016 TOTAL MEDTECH SALES (US$ MILLION)	FISCAL 2015 TOTAL MEDTECH SALES (US$ MILLION)
51	AGFA Healthcare	1206.15	1219.59
52	Carl Zeiss Meditec[33]	1204.35	1154.18
53	DJO Global	1155.29	1113.63
54	Fukuda Denshi[34]	1122.14	968.61
55	Align Technology	1079.80	845.50
56	Invacare Corp	1047.47	1142.34
57	Integra LifeSciences	992.07	882.73
58	NuVasive	962.07	811.11
59	Omron[35]	933.64	893.40
60	Straumann	931.50	831.21
61	Haemonetics[36]	886.11	908.83
62	Cochlear	861.26	708.43
63	Guerbet	858.47	542.32
64	Konica Minolta[37]	828.61	742.02
65	Myriad Genetics[38]	771.40	753.80
66	Cantel Medical	770.16	664.76
67	CONMED	763.52	719.17
68	Masimo Corp	694.63	630.11
69	Wright Medical Group[39]	690.36	405.33
70	Diasorin	629.98	553.95
71	Merit Medical Systems	603.84	542.15
72	DexCom	573.30	402.00
73	Globus Medical	563.99	544.75
74	Analogic Corp[40]	452.40	458.80
75	Hamamatsu Photonics[41]	449.54	377.50

[33]Year ends Sep 30 2016
[34]FY2017 vs FY2016 (year ends Mar. 31)
[35]Year ends Mar. 31. Healthcare business only.
[36]FY2017 vs FY2016 (year ends Mar 31)
[37]Healthcare business only
[38]FY2017 vs FY2016 (year ends June 30)
[39]First full year after Tornier merger
[40]Medical imaging + Ultrasound
[41]FY2017 vs FY2016 (year ends Sep 30). Medical Instrument sales only.

RANKING	COMPANY	FISCAL 2016 TOTAL MEDTECH SALES (US$ MILLION)	FISCAL 2015 TOTAL MEDTECH SALES (US$ MILLION)
76	Abiomed[42]	445.30	329.50
77	Heraeus Group[43]	442.29	395.84
78	Orthofix International	409.79	396.49
79	Jiangsu Yuyue Medical Equipment	396.29	334.80
80	Ypsomed	395.54	107.41
81	MicroPort Scientific	389.90	375.80
82	Cooper Companies Inc[44]	389.60	309.30
83	Accuray[45]	383.41	398.80
84	Natus Medical	381.89	375.87
85	ICU Medical	379.40	341.70
86	LePu Medical Technology	376.14	300.33
87	NxStage Medical[46]	366.38	336.12
88	AngioDynamics[47]	349.60	353.90
89	Hogy Medical[48]	339.73	302.16
90	RTI Surgical	272.87	282.29
91	Spectranetics[49]	270.82	245.96
92	Luminex	270.64	237.70
93	Exactech	257.57	241.84
94	Varian Medical Systems[50]	248.50	250.60
95	Horiba Ltd[51]	244.84	228.63
96	Cardiovascular Systems[52]	204.91	178.18
97	Stratec Biomedical Systems	204.60	163.02
98	Meridian Bioscience	196.08	194.83
99	Endologix[53]	192.93	153.61
100	Quidel	191.60	196.13

[42]FY2017 vs FY2016 (year ends Mar. 31)
[43]Health only.
[44]CooperSurgical business only
[45]FY2017 vs FY206 (year ends June 30)
[46]Agreed to be acquired by Fresenius in 2017.
[47]FY2017 vs FY2016 (year ends May 31)
[48]FY2017 vs FY2016 (year ends Mar 31)
[49]To be bought by Philips in 2017
[50]Imaging components business only; will be spun out as independent business post 2016
[51]Medical sales only.
[52]FY2017 vs FY2016 (year ends June 30)
[53]Completed merger with TriVascular Technologies in Feb 2016.

Will Brexit Negotiations Move To Devices Soon?

AMANDA MAXWELL amanda.maxwell@informa.com

With progress having at last been made in the first segment of political negotiations between the UK and the EU over Brexit, there is hope that the next stage will include steps toward agreement surrounding the future regulation of medical devices and diagnostics.

The news today of a breakthrough on some of the toughest political issues has been welcomed as the step away from a "hard Brexit," feared by many, where the EU and UK would essentially find themselves unable to reach any deal at all. Such an outcome would have meant no foundation on which to build further economic and regulatory agreements.

While certain issues still need ironing out, and the UK government continues to repeat the mantra that "nothing is agreed until everything is agreed," many aspects of the agreements reached after tough negotiations during the first week or so of December have been welcomed by those in the health sectors.

Because of these talks, the European Commission has recommended to the European Council to conclude that sufficient progress has been made in the first phase of the Article 50 negotiations with the UK. It will then be up to the European Council to decide at its meeting set for Dec. 14-15 if negotiations can proceed to the second phase to focus on establishing an EU-UK trade deal.

One particularly refreshing item of progress is that certain existing, mutual health-care arrangements will remain in place for the UK – at least for now. Most notably, this will include the European Health Insurance Card (EHIC) scheme, where citizens of each EU member state are entitled to health care free of charge (reimbursed by their own national health-care system subject to certain conditions) when in another EU member state.

DEVICES AND DIAGNOSTICS NEXT?

The UK Academy of Medical Sciences believes the scene is set for the next stage. "Now we must look forward to seeing the development of the next phase of negotiations and

> Negotiations should be completed by fall 2018 to allow good time for the Withdrawal Agreement to be concluded by the Council after obtaining consent of the European Parliament, and to be approved by the UK in accordance with its own procedures before March 29, 2019.

transition, particularly the future regulation of medicines, medical devices and diagnostics," the group noted in a statement.

There is likely to be an increased hope that the developing positive atmosphere will encourage a more patient-focused approach to deciding the future regulation of health-care products.

But no one should be naïve about how high the hurdles are and about what is at stake. Certainly, the medical device, IVD and pharma associations, alongside all others in the life-sciences sector, have been doing their homework and lobbying to inform governments how risky the outcome would be for patients if there was regulatory divergence – including the UK not fully adopting the EU's Medical Device and IVD Regulations.

The EU's largest medtech association, MedTech Europe, which has not yet commented on the latest progress, recently met with the European Parliament and Council to present its position. And it has just issued a press release featuring strong backing from other industry associations, as well as from Nicola Bedlington, secretary general of the European Patients' Forum.

In the release, Nathalie Moll, director general of the European Federation of Pharmaceutical Industries and Associations (EFPIA), says: "The life-sciences sector in the EU and UK are completely aligned in seeking future cooperation on the regulation and supply of medicines and medical technologies in the Brexit negotiations … We urge negotiators on both sides to move to the second phase as quickly as possible and agree on an adequate transition period and future cooperation after March 2019."

She goes on to warn that if not addressed in an appropriate and timely manner, Brexit will affect the supply, regulatory system and the monitoring of medicines and medical technologies for patients across the EU.

Medtech Europe says that the priorities now are to:

- Bring close cooperation between the EU and UK on the regulation of medicines and medical technologies to ensure that UK and EU patients will continue to have access to life-saving medicines and medical technologies.
- Establish a common framework for collaboration in research and information-sharing between the EU27 and the UK.
- Ensure that there are continued reciprocal health-care arrangements between the EU and UK.
- Develop strong coordination between the EU and UK on public health, including in pandemic preparation and disease prevention programs.
- Ensure EU and UK health professionals continue to benefit from mutually beneficial training and education opportunities, with automatic recognition of qualifications.

GOOD NEWS FOR RESEARCH

Meanwhile, Academy of Medical Sciences has pointed out that the Dec. 8 breakthrough is good news for medical research – considering that some 25% of medical research staff working in UK universities are non-UK nationals.

The academy also makes the point that the UK will be able to continue to participate in EU programs that run until 2020, such as Horizon 2020. "This greatly anticipated news will allow UK-based researchers to continue to benefit from the wide-reaching collaborative opportunities and funding that Horizon 2020 offers, the association says.

Published on 12/08/17

EMA Warns Device Sector That Relocation Could Hinder Device Approvals

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Work related to combination and borderline products could be put on hold during the Brexit-triggered relocation of the European Medicines Agency (EMA) from London to Amsterdam. That is the warning from Guido Rasi, executive director at agency during a recent press briefing.

The agency is going to be coping not only with the physical upheaval of the offices, but also with losing some staff who choose not to relocate to Amsterdam. It will also have to train new staff. All of this, while EMA is slated to new and updated services in the context of drug/device combinations and borderline products.

EMA confirmed to *Medtech Insight* that EU's new Medical Devices Regulation and IVD Regulation direct some new activities for the agency, such as the consultation of the EMA, in cases where consultation of one of the national drug authorities will not suffice, on:

- Borderline products;
- Systematically absorbed devices; and
- Companion diagnostics intended to be used with a medicinal product.

This comes in addition to EMA's existing role in the assessment of ancillary substances incorporated in high-risk, class III devices, which has been maintained in the new regulations.

An EMA spokeswoman subsequently said that "it is still too early to assess the impact of the relocation in relation to EMA's staffing, as we are not, for the moment, in a position to say how many staff will actually relocate".

She added, the EMA "will need to prepare for the implementation of these activities, and will have to carry out these procedures when the two regulations apply (2020 and 2022, respectively)."

This latest disclosure adds more uncertainty to those developing drug/device combination and borderline products.

Firms in that space are already facing challenges as the notified bodies they have worked with apply for designation under the Medical Device and IVD Regulations. These notified bodies may have worked in conjunction with the EMA in the past, for example, to support approval for the medicinal product element of a class III drug/device combination. But if a notified body is no longer designated in a particular area, that could force a manufacturer to have to try and change notified bodies, another minefield that the sector will need to navigate as a result of the overlapping timing of the new regulations and Brexit.

EMA must take up its operations in Amsterdam on March 30, 2019, at the latest, an "extremely tight deadline" in the agency's view. EMA Director Rasi notes: "Our internal surveys have shown that a large majority of EMA staff would be willing to move with the agency to Amsterdam. However even in this case, our activities will be impacted and we need to plan for this now to avoid the creation of gaps in knowledge and expertise."

EMA has been based in London, UK, since it was established in 1995. It currently employs nearly 900 staff members at its headquarters in Canary Wharf, London.

Published on 12/07/17

Malaysia Moves: Asian Medtech Associations Regulatory Networking November 2017, Part I

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[**Editor's note:** *In November,* Medtech Insight *sat down with Asia-based regulatory experts to discuss updates from the region in the second Medtech Associations Regulatory Networking event, sponsored by Asia Regulatory and Quality Consultancy (ARQon), and the Asia Regulatory Professional Association (ARPA).*]

The pressure is on medtech manufacturers in Malaysia to comply with new medical device legislation by the end of the year, but the government has not ruled out an extension. deadline

Malaysia's Medical Device Act 2012 (Act 737) is due to be in place fully as of Dec. 31, 2017. On July 25 of this year, Malaysia's Medical Device Authority (MDA) published a new regulation that set out the necessity of swift and timely compliance with the deadlines of Act 737, which became effective on June 30, 2013.

The new notification, "Full enforcement of registration requirements of medical devices under section 5 of Act 737," stipulated that as of Jan. 1, 2018:

- Manufacturers can only import medical devices that have MDA certification, and
- Acknowledgement letters issued by the MDA in the wake of Act 737's effective date, enabling device companies to maintain commercial activities in the interim, will be invalid for companies that have not acquired MDA certification by Dec. 31, bearing in mind the Oct. 31 document submission deadline.

Concerns have been expressed at the fast-approaching deadline. The recent Medtech Associations Regulatory Networking session raised the issue of any updates with regard to the full enforcement deadlines, and if an extension was under consideration at the MDA.

To date, the answer is that the authority is, in fact, working on the possibility of a timeline extension and is seeking justification for this. Industry has provided a white paper to the MDA asking for the agency to consider a one-year extension. The MDA itself is doing a survey on the readiness of companies to comply with Act 737 as of January 2018. *(Also see "Malaysian device system targets total life cycle regulation" - Medtech Insight, 7 Jul, 2014.)*

For its part, the local association is working with other medical device and trade associations to seek a moratorium of the enforcement date, and their findings were due to be sent to the MDA by the end of November.

UPDATE ON LABELING OF DEVICES

At a recent meeting with the MDA on the authority's draft labeling guidelines, industry representatives learned that the registration number, as shown in the Malaysia register of medical devices, will still need to be shown on labeling before the device can be placed on the market.

Written confirmation of this is still pending, but industry has been told that Aug. 7, 2018, is the enforcement date, and any products manufactured after this date will require the registration number appended to the label. This information was contained in an MDA circular issued in August 2016, giving a two-year transition period for compliance. *(Also see "Medtech Gets Two Years To Meet Labeling Rules In Malaysia" - Medtech Insight, 9 Aug, 2016.)*

In addition, the Bahasa Malaysia language will be required on all parts of the packaging, and not just on the instructions for use (IFU), as earlier understood by industry. But this is required only for home-use and OTC devices – not those intended for professional-only use. *(Also see "Asia Reg Roundup: Vietnam Decree, Malaysia Labels And More" - Medtech Insight, 16 Sep, 2016.)*

Further, class A (low-risk) medical devices are no longer required to have an IFU – but this must be justified in the product registration dossier.

The MDA has also issued a consultation on regulations for devices imported for exhibition purposes and demonstration devices. The consultation ran until mid-November; industry representatives are not aware of any special concerns.

MALAYSIA LEADS ON HALAL STANDARDS FOR DEVICES – INDONESIA, BRUNEI NOT FAR BEHIND

Finally, standards on voluntary halal certification of medical devices in Malaysia are currently being drafted, and are to be the focus of a second public forum soon. The target date for go-ahead is late 2017 – which may be too ambitious, insiders acknowledge. Nevertheless, the new requirement could be a reference and set precedent for other countries in South East Asia: If halal, which addresses adherence to Islamic law, is made a specific requirement in Malaysia, it could have an impact across the region.

Multinationals and well as local companies are monitoring the situation very closely. Indonesia has a draft bill on placing halal logos on all health-care products. Industry lobbying has succeeded in putting a hold on this for devices and lifesaving drugs for the time being; the priority locally is around food and consumer products. But once Malaysia's standard is released, it may lead to renewed activity in Indonesia, a prospect that industry has some concerns about.

Brunei is reportedly also looking at placing halal logos on medical devices – and that is even before it has a national device regulatory code in place. Malaysia may unleash a domino effect, industry representatives participating in the Medtech Associations Regulatory Networking discussion observed.

Published on 12/06/17

Singapore & Beyond: Asian Medtech Associations Regulatory Networking November 2017, Part 2

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Broad-scale medtech regulatory change is under way in Singapore, as part of a program designed to speed highly-innovative products into circulation and remove certain procedural steps for lower-risk products. *(Also see "Singapore To Make Major Medtech Regulatory Changes Under Economic Growth Plan" - Medtech Insight, 2 Jun, 2017.)*

In this context, the Health Science Authority (HSA), the Singapore regulator, continues to work on simplification for class A (low risk) products. It recently decided that class A sterile products (1s) no longer need registration, which will mean additional changes to Singapore's Medical Device Regulations. Imports of class A sterile products will be submitted and processed as non-sterile class A products.

Class A measuring devices (1m) have always qualified for simplified submissions and been exempted from product registration in Singapore. The logic of now lightening the regulatory pathway for sterile class A devices is part of a policy at the HSA to allocate more time to *de novo* technologies, like cell and gene therapy, which will be a focus at the authority for the next three years. It also wants to fine-tune its approach to other fast-developing areas of regulation like telehealth and 3D printing.

The class A sterile change is seen as a very pro-industry and pro-enterprise move, but it is not a case of the HSA relinquishing regulatory oversight. The agency will still have an overview of these devices entering Singapore by means of six-monthly import license updates, a process that allows the regulator to check what companies are bringing into Singapore in terms of class 1 devices.

Industry has additionally suggested a quicker method of regulation for IVD analyzers, which are subject to frequent software updates, and to reagent-listing updates at each occasion. Analyzers should instead be listed separately, industry recommends.

SINGAPORE DISTRIBUTION UPDATE

In October 2017, the HSA released a document intended to provide general guidance on SS 620: the 2016 Singapore Standard for Good Distribution Practice for Medical Devices (SS GDPMDS). The guidance, GN-33: Guidance on the Application of Singapore Standard, is shown here. Industry has been engaged in discussions around ongoing aspects, especially secondary assembly.

Starting now, there will be a three-year transition period, enabling companies to secure certification, by certified bodies that have been accredited by the Singapore Accreditation Council (SAC). Companies have until Nov. 9, 2020 to gain certification.

AMDC AND APACMED REG HIGHLIGHTS

The fifth Asean Medical Device Committee (AMDC) meeting, its H2 2017 meeting, was held in Indonesia where it was announced that Indonesia will implement GDPMD (CDAKB in the local language) for distribution, similar to the systems used in Singapore and Malaysia, but there are no timelines as yet. The country will also use a bilingual registration system for submissions – Bahasa Malaysia and English will be used.

It was also announced that the Philippines will use Common Submission Dossier Templates (CSDTs) for certain products, a development that should not impact industry. Thailand has also started using CSDTs this year for high-risk products, and reportedly plans to expand them to all products within five years.

The H1 2018 AMDC meeting is set for Singapore on April 4-6, with many ASEAN regulators expected to be present. As in Indonesia, the agenda themes will include sharing experiences on best practice in radiofrequency identification (RFID).

The very next major regional regulatory

event is the Asian Harmonization Working Party (AHWP) annual meeting in New Delhi, on December 4-8.

The Asia-Pacific Medtech (APACMed) regulatory track in early November followed directly after the Asia-Pacific Medtech Forum. *(Also see "Exec Chat: How Verb Surgical Will Deliver On Surgery 4.0" - Medtech Insight, 14 Nov, 2017.)* A standout presentation over the combined three-day event was reportedly Microsoft's description of hologram technology and virtual reality surgery for surgeons, the potential of big data and the controversial theme of how or when IT could replace physicians.

The regulatory debate at the meeting extended to the workload placed on regulators, with officials from Thailand, Cambodia, China's CMDA, Japan's PMDA, Vietnam's FDA, and Malaysia's MDA providing input. The AMDC chair passes next year from Malaysia to Singapore. The current Malaysian agency chair described the growing workload demands of a regulatory body, alluding to one aspirational MDA performance target of processing 70,000 medical device files per year. But full approval of all submissions in that workload would take 10 years, the MDA chair noted.

VIETNAM MULLS REGULATORY DEADLINE

For many, this illustrates the need to find appropriate ways of fast-tracking products through regulatory processes - low-

risk devices especially – which Singapore is broaching. And perhaps these experiences provide a good model for other agencies – such as those in Thailand and Vietnam – that are in the throes of setting up regulatory systems. They might have even fewer resources and lesser know-how than the MDA, suggested Jack Wong, head of ARPA, the Asia Regulatory Professional Association.

Vietnam has an aggressive timeline for its new regulatory system, calling for submission of all files by the end of this year, the start date of its new system. But in recent weeks, pressure had been growing for an extension of the deadline. Of the two schools of thought on this – should applicants plan for a postponement; or simply get on with timely compliance – participants in the Medtech Associations Regulatory Networking discussion advised the latter, safer option.

Published on 12/07/17

Draft Clinical-Decision-Support Software Guide Paves A Path, But May Need Some Work

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Scott Gottlieb and the US FDA came out with the next round of policy documents this week to build on the commissioner's oft-stated missions to help spark innovation in the digital-health space, but at least one of the texts, on clinical-decision-support (CDS) software, is getting some early pushback.

The agency issued a total of two draft and one final guidance document Dec. 7 outline expectations and, in particular, identifying software products that fall outside of FDA requirements for active regulation.

"We're finding that in some parts of our regulatory portfolio, our traditional approach to overseeing certain health-care products does not easily fit the types of innovations that are being developed," Gottlieb said. "In these cases, we must adapt and evolve our policies to make sure we continue to provide a gold standard for oversight, while enabling advancement of beneficial innovations and greater consumer access to technologies that can improve their health."

On the same day as FDA released the guidances, the commissioner also spoke before a Senate committee hearing about the agency's goal is to "go beyond" health-software provisions in the 21st Century Cures Act to allow FDA to exclude from regulation most digital devices and clinical decision software. *(Also see "US FDA's Gottlieb Takes Digital Device Questions From Senators At Cures Hearing" - Medtech Insight, 8 Dec, 2017.)* But an industry stakeholder suggested in an interview that, particularly for professional-use software, FDA did not go far enough beyond the statute.

In addition to the CDS draft guidance, the agency issued a draft specifically outlining how it plans to implement the software provisions of the Cures Act and a final guidance adopting an International Medical Device Regulators Forum document on clinical guidelines for "software as a medical device." [**Editors' note:** *Look for more detailed upcoming coverage of these latter two documents soon in* Medtech Insight.]

TO REGULATE, OR NOT TO REGULATE

In the CDS draft guidance, using the mandates under the Cures Act, FDA tries to clarify what types of CDS will no longer be defined as a medical device and be outside the scope of the agency's oversight. For instance, software that allows physicans to independently review their clinical recommendations would no longer be regulated by FDA.

> "The future of clinical decision support software is in machine learning and other forms of complex algorithms that add to the knowledge of physicians," says the CDS Coalition's Brad Thompson. "And FDA seems to be saying that all such software will be regulated regardless of risk. That's extremely troublesome"

The draft includes several examples of CDS that FDA would not regulate, including, for instance, a piece of software that suggests to a provider to order liver function tests before starting statin medication in a manner that is consistent with clinical guidelines and approved drug labeling.

"CDS has many uses, including helping providers, and ultimately patients, identify the most appropriate treatment plan for their disease or condition," said Gottlieb. "This type of technology has the potential to enable providers and patients to fully leverage digital tools to improve decision making. We want to encourage developers to create, adapt and expand the functionalities of their software to aid providers in diagnosing and treating old and new medical maladies."

However, the commissioner emphasized that the agency will continue to enforce oversight of CDS products that are intended to process or analyze:

- Medical images;
- Signals from in vitro diagnostic devices; or
- Patterns acquired from processors like an electrocardiogram that use analytical functionalities to make treatment recommendations.

"For example, we would continue to oversee software that analyzes data from a patient's spinal fluid test to diagnose tuberculosis meningitis or viral meningitis," Gottlieb explained. "These are areas in which the information provided in the clinical decision software, if not accurate, has the potential for significant patient harm, and the FDA plays an important role in ensuring the safety and effectiveness of these products."

PDS: SOFTWARE FOR PATIENTS, CAREGIVERS

The guidance also carves out a section of lower-risk software called patient decision support software (PDS) that is intended for use by patients and caregivers. FDA acknowledges PDS is not explicitly defined in the Cures Act, but the agency proposes following similar guidelines to those proposed for CDS to determine when they require FDA oversight.

One example cited in the guidance of a lower-risk PDS the agency would not regulate are apps that help patients take their medication on time. However, there are certain PDS software that could fall under the agency's purview.

"PDS software that does not clearly allow independent review of the recommendation by the patient or a caregiver would continue to be subject to the FDA's active oversight," said Gottlieb. "This might include a warfarin monitoring device that makes recommendations for dosing based on the outcome of a home blood test.

"We believe our proposals for regulating CDS and PDS not only fulfill the provisions of the Cures Act, but also strike the right balance between ensuring patient safety and promoting innovation," he added.

A 'DISCOURAGING' DIRECTION

Despite FDA's stated attempt to issue the guidance in a way that protects patients but also helps industry foster innovation, at least one industry advocate, who advises a group of CDS manufactures, says the draft would add undue burdens on CDS developers.

Bradley Thompson, general counsel for the CDS Coalition, said he's unhappy with how FDA has written the guidance, though he cautioned that he couldn't speak on behalf of the coalition yet because they are still evaluating the text.

Thompson, an attorney with Epstein Becker & Green, says he was excited for the guidance, which has been six years in the making. But after reading the document, he was disappointed. While there are parts of the guidance that he thinks would be helpful to CDS developers, overall, he doesn't think the agency adopted the risk-based approach he'd hoped for.

Thompson says there are parts of the guidance he supports, including the carve-out for PDS products. He also praised the fact that the FDA's drug center signed on to the guidance, which may indicate an understanding by the agency of the role that CDS plans in recommending drug dosage and use, though the coalition would like to see a specific CDER guidance on the issue.

And he acknowledges that certain high-risk software needs to be regulated. Examples of products that warrant oversight, according to Thompson, are those to help make decisions about chemotherapy treatments, which could lead to patient harm or death if they aren't found to be safe and effective.

But there are other low-risk CDS products that could would face unnecessary hurdles under the proposed guidance, he said. An example of an item that would likely fall under oversight based on the guidance, but shouldn't according to Thompson: software that uses data from patients for predicting a risk score in healthy populations for developing a migraine as a tool to support medical counseling.

"What I think many of us in industry were hoping for, was an effort by FDA to distinguish high from low risk as a basis for regulation," said Thompson. "We didn't get that. Worse, it appears based on the guidance that FDA is not interested in drawing that line."

FDA does state in the draft guidance that it will maintain enforcement discretion for certain mobile medical apps and certain PDS products. Thompson, however, notes the agency's 2013 mobile medical apps guidance specifically states it does not apply to CDS products, and that industry should instead look to the new CDS draft guidance for clarity.

Thompson also argues the International Medical Device Regulators Forum issued a framework in 2014 for software as a medical device (SAMD) and while FDA issued a final guidance alongside the CDS draft guidance specifically stating it was following the IMDRF guidelines, the agency did not apply that risk-based framework to CDS products.

"Instead, for the most part, FDA simply stuck with the 21st Century Cures Act framework that exempts certain software so long as the physician user can independently review the basis for the recommendation. Of course FDA needed to abide by the statute, but it didn't need to stop there," he said. "Indeed, FDA recognized that when it extended the statutory language to include software sold to patients and caregivers [PDS]. That was good. But with regard to professional users, FDA stopped at the edge of the statute."

MACHINE-LEARNING GETS A RAW DEAL?

The bottom line for Thompson is, according to the guidance, software that doesn't provide a reasonable basis for reviewing the recommendations it provides will always be regulated, regardless of level of risk. This could include products that use machine-learning algorithms to determine if a patient has a cold. Even though such software would be low risk, it's not something that physicians can review because of the complicated algorithm and, thus, would be regulated by FDA.

"That's what's discouraging about this. The FDA guidance seems to be fine for historical software that simply takes existing clinical guidelines and applies them formulaically to patient data," he said. "But the future of clinical decision support software is in machine learning and other forms of complex algorithms that add to the knowledge of physicians. And FDA seems to be saying that all such software will be regulated regardless of risk. That's extremely troublesome."

Recently, Thompson's coalition also published its own guidelines as a way to self-regulate the sector and head off FDA. The CDS Coalition met with FDA to express its thinking, including on how companies could get products to market that use complex machine-learning algorithms. But in the draft guidance, the agency seems to have "ignored the topic" according to Thompson. *(Also see "Industry Issues Guidelines To Head Off Potential CDS Software Regs" - Medtech Insight, 30 Aug, 2017.)*

Thompson also complains that FDA doesn't provide an explanation for why the CDS and PDS examples provided in the guidance will or won't be regulated, and there's not a lot of diversity in the examples of the products FDA provided.

"The section on patient decision support suggests that the simple test is whether patients – which presumably include those who might only have a sixth-grade education – can understand the basis for the software. That's not a very clear standard. And it is not risk-based," added Thompson. "You could have again software that uses machine learning simply to help patients decide how best to treat a cold – do you starve a cold or feed a cold – and it would be regulated if the patient can't understand the algorithm. If a patient has a sixth-grade education, it wouldn't take a very complicated algorithm to exceed that limit."

Published on 12/08/17

Planned US Device-Center Reorg Will Be Organized Around Device Types

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A planned reorganization of US FDA's device center would see review staff organized by device type, rather than by stage in the device cycle. Its scheduled to get off the ground in 2018.

CDRH Director Jeff Shuren first announced plans for a new "super office" that would break down barriers between current review, compliance and surveillance offices in September. *(Also see "'Super Office' To The Rescue: FDA's Device Center Is About To Undergo A 'Total Product Life Cycle' Makeover" - Medtech Insight, 29 Sep, 2017.)* Sean Boyd, deputy director for regulatory affairs in the device center's Office of Compliance, provided some more color on the proposal Dec. 5 during a panel discussion at the Food & Drug Law Institute's enforcement, litigation and compliance conference in Washington, DC.

The current structure in which separate FDA staff oversee premarket device approval and post-market monitoring and enforcement can make it difficult for reviewers in different offices to share information, Boyd said.

"Getting more specific within offices to focus on groups of like technologies will let us have all the people, regulatory tools and knowledge to understand both what's going on in the industry sector and at the specific company," Boyd said. "We believe this will create organic connections within the agency so people can converge on a specific device area, and that we will gain a streamlined review process by bringing people and ideas together."

> FDA anticipates the new super office will contain seven device-specific offices, and that the reorganization, on its own, will be not increase or decrease overall device-center staffing levels.

The approach will also allow for regulatory staff to develop a fuller picture of the device, firm and industry, and will let FDA streamline its decisions and processes. CDRH has offered a total product lifecycle approach for diagnostics since 2000, when the Office of In Vitro Diagnostics and Radiological Health (OIR) was formed. The new super office would extend the approach to other devices.

Specifically, the proposal will combine the Office of Device Evaluation, Office of Compliance, Office of Surveillance and Biometrics and OIR into a single office that will then be divided by device types. Bill Maisel, deputy center director for science and acting director of the Office of Device Evaluation and the Office of Compliance, is expected to head the structure.

The proposed reorganization will go forward in 2018 after approval from the Department of Health and Human Services, FDA spokeswoman Deborah Kotz said. She anticipates it will include seven device-specific offices, and that there will be no increase or decrease to device-center staffing levels due to the reorganization. However, Kotz noted, the device center already planned to add staff in 2018 to meet its user-fee agreement commitments.

TALK INSTEAD OF ENFORCEMENT?

Boyd also discussed other ongoing device-center efforts, such as a plan to implement a system that will let manufacturers offer feedback to the agency after inspections addressing any observations made on the FDA-483. If FDA is confident a company's improvement suggestions made at that time will be successful, the

agency may opt to hold a meeting or issue an untitled letter instead of a warning letter, Boyd said.

"It may be that firms who put an adequate plan in place or have already taken steps to address problems, we can tailor our regulatory approach and meter down traditional compliance activities," he said.

But Boyd further cautioned that FDA will still expect companies to be fully responsive to inspector's findings, which include applying the agency's observations "systemically" to address broader issues. Additionally, he said that FDA wanted businesses to provide clear, well-organized responses that address the specific issues at hand, rather than handing over "stacks of paper." He tied that to the agency's least-burdensome enforcement approach.

"Several concepts within least burdensome say that we should ask for the minimum information to address concerns," Boyd said. "But the industry also has obligation to submit its least-burdensome information to FDA."

Boyd also offered an update on several of FDA's ongoing pilot programs. For example, he said that 565 of the 714 sites now enrolled in the Medical Device Single Audit Program (MDSAP), which allows a single inspection to cover multiple jurisdictions, have joined over the course of 2017. And of the 354 inspections performed to date, 130 have ended with "no action indicated." A further 223 required voluntary action, while only one indicated official action was needed, he said.

FDA is also offering a PMA Critical to Quality pilot in which manufacturers who meet certain qualifications can engage with FDA early in the submission process, as well as a voluntary medical device and product quality pilot that integrates a maturity model to drive continuous improvement. *(Also see "5 Ongoing US FDA Device Center Pilot Programs: A Listing" - Medtech Insight, 27 Nov, 2017.)* Choosing which programs to enroll in is a "business decision," Boyd said.

Published on 12/08/17

New Path For 510(k)s On US FDA's FY 2018 Guidance-Priority Plan

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US FDA's device center plans to establish a new, voluntary pathway for medtech sponsors to gain 510(k) clearance for some products that puts more emphasis on performance criteria and less on predicate- device comparisons. The proposed approach will be spelled out in a draft guidance slated for release in the first quarter of 2018, according to agency Commissioner Scott Gottlieb.

"This pathway would be available for pre-specified categories of mature devices – those for which safety and performance criteria that meet or exceed the performing of existing, legally marketed devices can be identified," Gottlieb explained in a Dec. 11 blog post. The draft guidance will be known as "Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence Through Performance Criteria."

"This approach will make it easier to FDA to conform its framework for evaluating new products to international, consensus standards where such standards exist," he added.

The prospect of moving 510(k)s away from a reliance on comparisons to predicate has been raised in the past as part of 510(k)-reform debates, but the prospect of such a fundamental change to the program has been resisted by the agency. *(Also see "Scrutinizing Substantial Equivalence: 510(k) Predicate Standard Questioned At FDLI" - Medtech Insight, 22 Apr, 2015.)* This proposal would appear to be a step in the direction of avoiding the need for predicates in some cases.

Gottlieb noted that FDA wants to establish the new approach because, currently, predicate devices that new products must be compared to "are sometimes 40 years old," and such direct comparison testing creates burdens for 510(k) applicants. This is especially true "when many new devices are designed in novel ways, using more advanced technologies," Gottlieb remarked.

The 510(k) draft guidance is one 10 draft documents that the device center has prioritized in its "A-List" for FY 2018. The other topics potentially slated for the remaining nine months of the fiscal year are:

- Export certificates;
- Multifunctional device products: policy and consideration;

- The "least burdensome" provisions: concept and principles;
- Humanitarian devices exemption (HDE) program;
- 510(k) third party review program;
- Requests for feedback and meetings for medical device submissions: The Q-submission program;
- The application of acceptable uncertainty to support marketing authorization decisions for medical devices;
- Principles and procedures for the recognition and/or withdrawal of voluntary consensus standards; and
- Validation of automated process equipment software.

Meanwhile, FDA plans to release the following final guidances, which the agency considers to be on its "A-List" for FY 2018:

- Medical device accessories: describing accessories and classification pathway for new accessory types (revision);
- Unique device identification: policy regarding compliance dates of class I and unclassified devices;
- Appropriate use of voluntary consensus standards in premarket submissions for medical devices;
- Considerations for design, development, and analytical validation of next generation sequencing (NGS)-based *in vitro* diagnostics (IVDs) intended to aid in the diagnosis of suspected germline diseases;
- Use of public human genetic variant databases to support clinical validity for genetic and genomic based *in vitro* diagnostics.

FDA also maintains a second-tier priority list of guidances (B-List), which it intends to publish – as resources permit – in FY 2018. Among the final guidance topics on this list: human-factors list of high-priority devices; benefit-risk factors to consider when determining substantial equivalence in 510(k)s with different technological characteristics; and principles for co-development of an *in vitro* companion diagnostic device with a therapeutic product.

Draft guidance topics on FDA's B-List are: pre-market submissions for patient-matched guides to orthopedic implants and replacement reagents for technologically similar instruments for *in vitro* diagnostic devices.

FDA could also decide to update older final guidances under its "retrospective review" policy. This time around, the agency is review guidance documents finalized in 1988, 1998, and 2008, FDA said on its webpage on planned final and draft guidances.

Comments on FDA's guidance priority list can be submitted under docket no. FDA-2012-N-1021.

Published on 12/11/17

CONTINUED FROM PAGE 11

could provide one of the safest therapies for psoriasis patients if found to be successful. "The main benefits of a bioelectronics therapy is that it's extremely targeted and gentle. There are no side effects apart from maybe mild skin irritation in some users," Pal said.

Earlier this year, Thync conducted a pilot study to determine the impact its device could have in treating the skin condition. The trial recruited 28 subjects ranging from mild to severe psoriasis – 18 in the treatment group and 10 in the sham control group. The patients provided a self-assessment on their improvement in appearance in terms of redness, scaling and itchiness and also supplied photographs of their affected area.

Thync reported positive results, with the study showing that compared to the placebo group, patients using Thync's neuromodulation technology had a significant reduction in redness, scaling, and itchiness of their plaque psoriasis after four weeks. There were no reported side effects and 15 of the 18 subjects in the treatment group (83%), reported at least a 50% reduction in psoriasis symptoms after four weeks. Six patients out of 18 reported more than a 75% reduction of these symptoms. In comparison, after four weeks, only 20% within the active placebo control group reported at least a 50% reduction in symptoms.

The difference in psoriasis symptom improvement between the treatment and control groups was "highly statistically significant" and both groups included patients with mild to severe psoriasis. "All the severe patients, saw at least a 50% improvement which shows that at least our technology is capable of possibly treating the most severe case," said Pal.

Goldwasser said "The results were striking. For a third of patients to see such a significant improvement in four weeks is very quick and you can look at trials for the best drugs out there for psoriasis and they usually take three or months to reach their plateau response. We would expect that because of the disease processes involved that people staying on using our technology would improve in one or two months so to see that improvement in just one month is really significant,"

Thync said the only drawback of the study was the self-assessment stage which tends to correlate well in dermatological assessments of psoriasis. In subsequent clinical trials, the effectiveness will be assessed independently by dermatologists.

Nevertheless, Thync is looking forward to this next focus for its technology. The company is gearing up for more clinical trials in 2018, which will be held at the University of California – San Francisco, Psoriasis and Skin Treatment Center. "We've already been talking to dermatologists and the key opinion leaders in the field and we believe we will have an early set of adopters for our technology, but it requires very clear evidence from clinical studies so that's what we're doing next," Goldwasser said. "Once the doctors see our solid clinical evidence, they will be very excited to take up our technology."

Published on 12/11/17

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