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News We're Watching: UK Software Guidance, FDA Approvals, Halyard Mask Warning

by Brian Bossetta

Abbott landed a surprise US FDA approval for the FreeStyle Libre 3 glucose monitoring system. Also this week: updated guidance documents on software (UK) and angioplasty catheters (US), FDA clearances for Candesant and Moximed, new regulatory requirements for spinal spheres, and a warning on Halyard masks.

FDA Approves Abbott's FreeStyle Libre 3 Reader

The US Food and Drug Administration has approved a new standalone reader device for Abbott's FreeStyle Libre 3 integrated glucose monitoring system, the company announced on 14 April.

The FreeStyle Libre 3 reader offers an alternative to the FreeStyle Libre smartphone app. It connects to the sensor on the user's arm and displays glucose readings on a "large, bright and easy-to-read screen."

In a 14 April note, Wells Fargo analyst Larry Biegelsen pointed out that the FDA approved the new reader device sooner than the company anticipated, so the company will probably launch it in the US market in the second half of 2023.

Now that FDA has cleared the standalone reader, the company is working with the Centers for Medicare and Medicaid Services to put FreeStyle Libre 3 on Medicare's list of covered glucose monitor devices.

The reader is powered by a common rechargeable lithium-ion battery and the company stresses that the user manual for the FreeStyle Libre 3 reader provides details on how to safely store, charge and use the device, including instructions to always use the Abbott-provided USB cable

and power adapter.

Abbott has received reports of devices overheating when plugged into the wrong adapter. (Also see "*News We're Watching: Abbott FreeStyle Libre Recall, Medtronic Partners With DaVita, Free SBOM Software*" - Medtech Insight, 7 Apr, 2023.)

UK Updates Software And AI Guidance

The Medicines and Healthcare products Regulatory Agency (MHRA) published *updated guidance* on 6 April around its regulatory framework for software and AI medical devices.
In the update, the medtech regulator describes how a dedicated "Software Group" will be responsible for taking steps to ensure that software and AI-based medical products are safe for use by UK patients.
The group will assist with pre-market and post-market enquiries from manufacturers; conduct technical file reviews and surveillance activities; review evidence and documents from clinical investigations; and ensure that regulation is fit-for-purpose.
The update adds to the MHRA's regulatory roadmap for software and AI medical devices, published in October. (Also see "*'Project Glass Box' - UK Reveals Roadmap For AI Medtech Regulation*" - Medtech Insight, 19 Oct, 2022.).

Do Not Use Certain N95s From O&M Halyard, FDA Warns

An FDA *safety communication* recommends consumers, health care providers, and facilities to not use certain surgical N95 respirators manufactured by O&M Halyard, and to use caution with certain surgical masks and pediatric face masks by O&M Halyard.

The FDA says it is aware of laboratory test results that show certain models of O&M Halyard surgical N95 respirators, surgical masks, and pediatric face masks do not meet quality and performance expectations and may not provide expected fluid barrier protection to the wearer. The FDA is continuing its evaluation.

The agency's warning provides a list of surgical N95 products from the company to stop using, recommendations for consumers, health care providers, and facilities, the actions the FDA is taking to correct the problem, and instructions for reporting problems to the FDA.

FDA Clears Candesant Biomedical's Brella Sweat-Control Patch

The US Food and Drug Administration has granted de novo clearance to Brella, the first and only three-minute sweat control patch.

Tennessee-based Candesant Biomedical will launch Brella in select US markets beginning in a few months. The Candesant Brella Early Experience Program will target health care providers that offer aesthetic services.

Brella is designed to treat primary axillary hyperhidrosis with targeted alkali thermolysis technology. The non-invasive patch is designed to be applied in a physician's office and lasts up to four months.

The patch has a sodium sheet with an adhesive overlay. According to the company, the sodium in the patch reacts with water in sweat to generate localized heat that causes the sweat glands to reduce sweat production.

"Satisfaction with current treatments is low, and 80% of consumers are seeking new treatments to manage excessive underarm sweat," Candesant CEO and founder Niquette Hunt said. "Brella provides a new option for a common condition that curtails activities, stains clothes, causes frustration and embarrassment, undermines confidence, and has been inadequately treated for far too long."

Moximed's Misha Knee Shock Absorber Wins FDA Clearance

The US Food and Drug Administration has cleared Moximed's Misha knee system for people with medial knee osteoarthritis who have failed to find pain-relief with other surgical and non-surgical treatments.

Misha is a subcutaneous implantable shock absorber that "unloads" the knee. *Two-year results of the 81-patient Calypso Study* showed Misha was superior to high tibial osteotomy surgery for the primary composite endpoint of the trial, which included pain, function, specific adverse events, integrity of implant or hardware, and conversion to subsequent surgery.

Final Guidance Issued On Specialty Angioplasty Catheters

The FDA has published its final guidance on specialty catheters used to treat narrowed blood vessels in the arms and legs.

Published on 14 April, the document, "Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters – Premarket Notification (510(k)) Submissions," provides the FDA's recommendations on non-clinical testing, animal and clinical studies, and labeling to support premarket submissions for these devices.

For premarket submissions, the FDA recommends identifying the device by the applicable regulation number and product code based on device type as provided by the agency in the document.

The agency further recommends submitters identify all components and accessories, including packaging, with a clear description of how the device is utilized to achieve the intended use in the intended anatomy; provide a photograph, as well as an engineering drawing with relevant dimensions, tolerances, and components labeled, of the device; describe the technical and performance specifications with a brief description of the device design requirements; and provide a list of all components, their respective materials of composition, and their patient-contacting classification.

The agency also reminds manufacturers to compare their new device to a similar legally marketed predicate device to support its substantial equivalence. This comparison should demonstrate how the new device is both similar to and different from the predicate.

PMA For Spinal Spheres Required Starting 1 May

Spinal spheres for use in intervertebral fusion procedures are class III devices and will need a premarket application (PMA) starting 1 May, says a new rule from the FDA.

Sponsors who plan to market these spinal spheres are required to submit a PMA within 30 months of this date. Spinal spheres have been waiting a proper classification for some time now—in late 2021, the agency proposed a class III designation for the devices based on a recommendation from the FDA Orthopedic and Rehabilitation Devices Panel. (Also see "*FDA Action-Item List Shows Plans To Revamp De Novo, Combo Product, QSR Regs, And More*" - Medtech Insight, 23 Jul, 2020.)

According to the FDA, there are no spinal spheres currently marketed. This, in combination with the FDA's findings that these devices cause "unreasonable risk of illness or injury," informed the FDA's class III designation and 30-month time frame.

Illumina And Henry Ford Team Up To Tackle Heart Disease

DNA sequencing firm Illumina and Detroit-based not-for-profit healthcare organization Henry Ford have joined forces to assess the impact of genomic testing cardiovascular patients, Illumina recently *announced*.

CardioSeq, the first study under the partnership, will include 1,500 patients receiving care from

the Division of Cardiovascular Medicine at Henry Ford. During this project, researchers will investigate the use of next-generation sequencing tests, including whole-genome sequencing (WGS), to assess their impact on clinical care.

Genetics play a key role in determining risk for developing heart disease as well as how a patient might respond to common medications, Illumina said. The study will use an accredited clinical test developed by Illumina that uses WGS to create a comprehensive cardiovascular genomic profile, which can provide clinicians and patients with a more complete picture on which they can base risk management and care planning decisions, facilitate early diagnosis, and reduce unanticipated side effects, tests, and medical visits.

Alzheimer's Test Improves Accuracy Of Diagnosing and Predicting The Disease, Studies Show

St. Lous-based C2N Diagnostics says that *two research studies* demonstrate the ability of its Precivity AD2 test to measure amyloid plaques in the brain, an established marker of Alzheimer's disease.

C2N Diagnostics announced the findings at the annual AD/PD 2023 International Conference on Alzheimer's and Parkinson's Diseases in Gothenburg, Sweden.