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Enforcement Policy for Infusion Pumps and Accessories During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

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Guidance for Industry and Food and Drug Administration Staff

April 2020

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or the Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to https://www.regulations.gov. All comments should be identified with the docket number FDA-2020-D-1138 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders," available at https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders and the FDA webpage titled "Search for FDA Guidance Documents" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number 20022 and complete title of the guidance in the request.

Questions

For questions about this document, contact 1-888-INFO-FDA or CDRH-COVID19-InfusionPumps@fda.hhs.gov.

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Guidance for Industry and Food and Drug Administration Staff

I. Introduction

The Food and Drug Administration (FDA or the Agency) plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to provide a policy to help expand the availability and remote capabilities[1] of infusion pumps and their accessories for health care professionals during the COVID-19 pandemic.

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service (PHS) Act.

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March

[1] For the purpose of this guidance, the term "remote capabilities" refers to remote monitoring and/or remote manual control of infusion pumps. This guidance excludes scenarios where sustained infusion therapy is provided through a physiological closed loop or similarly developed closed loop system.

25, 2020, titled "Process for Making Available Guidance Documents Related to Coronavirus Disease 2019," *available at* https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[2] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[3]

FDA believes the policy set forth in this guidance may help address these urgent public health concerns by helping to expand the availability and remote capabilities of infusion pumps and their accessories during COVID-19 for patients requiring continuous infusion therapy.

III. Scope

The enforcement policy described in this guidance applies to the following infusion pumps and their accessories used to treat patients who require continuous infusion therapy during the COVID-19 public health emergency (See Table 1):

[2] Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx).
[3] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

Table 1

Classification Regulation	Device Type	Product Code[4]	Class
21 CFR 880.5725	Infusion Pump	FRN	II
21 CFR 880.5725	Patient-controlled analgesia (PCA) Infusion Pump	MEA	II
21 CFR 880.5725	Infusion Pump Accessories	MRZ	II
21 CFR 880.5725	Infusion Safety Management Software	PHC	II

Some infusion pumps have the potential to be connected to a wireless network through Bluetooth, Wi-Fi, or cellular connection to transmit a patient's data directly to their health care provider.

The enforcement policy described in this guidance also applies to the following accessories when used with the infusion pumps described in Table 1 (See Table 2):

Table 2

Classification Regulation	Device Type	Product Code	Class
21 CFR 868.5120	Short term intraspinal percutaneous catheter	MAJ	II
21 CFR 880.5025	I.V. container	KPE	II
21 CFR 880.5200	Therapeutic intravascular catheter, short-term less than 30 days	FOZ	II
21 CFR 880.5200	Midline catheter	PND	II
21 CFR 880.5210	Administration set securement device	PUK	I (exempt)[5]
21 CFR 880.5420	Pressure infusor for I.V. bags	KZD	I (exempt)[6]
21 CFR 880.5440	Intravascular administration set	FPA	II
21 CFR 880.5440	I.V set stopcock	FMG	II
21 CFR 880.5440	Infusion line filter	FPB	II
21 CFR 880.5440	Check valve, retrograde flow (in-line)	MJF	II
21 CFR 880.5440	Administrations sets with neuraxial connectors	PWH	II

[4] For more information see the Product Classification Database at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm.

[5] These devices are exempt from submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, subject to the limitations in 21 CFR 880.9. FDA clearance is not required before marketing the device in the United States; however, manufacturers are required to register their establishment under 21 CFR Part 807.

[6] *Ibid*.

21 CFR 880.5440	Neuraxial administration set - intrathecal delivery	PYR	II
21 CFR 880.5445	Intravascular administration set, automated air removal system	OKL	II[7]
21 CFR 880.5570	Non-coring (Huber) needle	PTI	II
21 CFR 880.5725	Electronic intravascular infusion controller	LDR	II
21 CFR 880.5965	Implanted subcutaneous intravascular port & catheter	LJT	II[8]
21 CFR 880.5965	Implanted subcutaneous apheresis port	PTD	II
21 CFR 880.5970	Therapeutic intravascular catheter, long-term greater than 30 days	LJS	II[9]
21 CFR 880.5970	Implanted subcutaneous securement catheter	OKC	II
21 CFR 880.5970	Long-term percutaneous implanted intravascular catheter accessory for catheter position	OMF	II
21 CFR 880.6990	Infusion stand	FOX	I (exempt)[10]
21 CFR 882.5550	Implanted subcutaneous intraventricular port & catheter	LKG	II

IV. Policy for Modifications to FDA-Cleared Devices

FDA believes it is important to help facilitate availability of the devices listed above, which includes large volume parenteral (LVP) infusion pumps, syringe infusion pumps, PCA infusion pumps, and ambulatory infusion pump devices, and their accessories, in order to support patients who require sustained infusion therapy in the context of the COVID-19 public health emergency. Patients infected with COVID-19 may require continuous infusion of medications, nutrition, and/or other fluids. As such, FDA recognizes the need to help increase access to an adequate supply of devices to treat patients who need these therapies and to help foster technologies that maintain a safer physical distance between the health care provider and patient affected by COVID-19.

Wherever possible, health care facilities should use FDA-cleared infusion pumps and accessories to

[7] This classification regulation is subject to special controls. See 21 CFR 880.5445(b). The special controls associated with this classification regulation remain in effect during the declared public health emergency.
[8] This classification regulation is subject to special controls. See 21 CFR 880.5965(b). The special controls associated with this classification regulation remain in effect during the declared public health emergency.
[9] This classification regulation is subject to special controls. See 21 CFR 880.5970(b). The special controls associated with this classification regulation remain in effect during the declared public health emergency.
[10] These devices are exempt from submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, subject to the limitations in 21 CFR 880.9.

provide infusion therapy, or a device authorized by an Emergency Use Authorization (EUA).[11] Recognizing that such devices may not always be available, and to help ensure the availability of the greatest possible number of devices for this purpose, as described in more detail below, FDA does not intend to object to limited modifications to the indications, functionality, hardware, software, design, or materials of FDA-cleared devices used to support patients who require continuous infusion therapy, without prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81,[12] for the duration of the public health emergency. This policy applies where a modification is made to the device that triggers the requirement that a manufacturer submit a new premarket notification [510(k)] to FDA. Examples of such changes could include a change or modification in design, intended use, material, chemical composition, energy source, or manufacturing process.

More specifically, this policy will create more flexibility for manufacturers that make device modifications to address manufacturing limitations or supply shortages related to the public health emergency. Examples may include:

- Changes to the infusion pump motor to allow an alternate supplier to meet the required design specifications, or
- Enabling an alternate supplier of infusion pump accessories to meet the established performance of the FDA-cleared device.

We believe this approach will help manufacturers that want to add production lines or manufacture at alternative sites which may have different manufacturing equipment to increase manufacturing capacity and supply and reduce supply chain interruptions and manufacturing bottlenecks.

A. Modifications to FDA-Cleared Indications or Functionality

In developing this policy, FDA's intent is to foster the continued availability of safe and effective medical devices while being flexible regarding modifications made to infusion pumps and their accessories, in response to the COVID-19 public health emergency.

As noted above, wherever possible, health care facilities should use FDA-cleared infusion pumps to treat patients who require continuous infusion therapy. However, for the duration of the public health emergency, to help foster the wider availability of devices for patients in need of continuous infusion therapy, and to help reduce healthcare provider exposure to patients affected by COVID-19, FDA does not intend to object to modifications to the FDA-cleared indications or functionality of these devices, without prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81 where the modification will not create an undue risk in light of the public health emergency. Examples of circumstances where FDA currently believes a modification would not

[11] For more information about FDA's EUA process, see the FDA guidance "Emergency Use Authorization of Medical Products and Related Authorities," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities.

[12] For further guidance on modifications that trigger the requirement that a manufacturer submit a new premarket notification (510(k)) to FDA, refer to "Deciding When to Submit a 510(k) for a Change to an Existing Device: Guidance for Industry and Food and Drug Administration Staff," https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device.

create such undue risk include:

1) Remote monitoring and/or manual control of infusion pumps to manage the care of a patient without physically entering a patient's room (e.g., remote control for manually turning on/off alarm settings and starting, stopping, or changing infusion parameters, remote monitoring of pump alarms, functions, and status);
2) Transfer of electronic drug library information (i.e., automatic programming) over a wireless or wired network connection;
3) The use of infusion pumps not indicated for ground and/or air transport for meeting the needs of patients who need to be transported, when the manufacturer conforms with IEC 60601-1-12:2014: *Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*; and
4) The use of infusion pumps for patient populations (e.g., pediatrics) not explicitly referenced in the device labeling.

Examples of circumstances where FDA currently believes a modification would create such an undue risk include:

1) Labeling modifications that change the device's use in a magnetic resonance (MR) environment; and
2) Implementation of physiological closed loop control systems.

B. Hardware, Software, Design, and Material Changes to FDA-cleared Infusion Pumps and Accessories

Wherever possible, health care facilities should use FDA-cleared infusion pumps and accessories to treat patients who require continuous infusion therapy. However, for the duration of the public health emergency, in order to help foster the wider availability of devices for patients in need of continuous infusion therapy, and to help reduce healthcare provider exposure to patients affected by COVID-19 and to help manufacturers respond to potential device component disruptions in the supply chain, FDA does not intend to object to limited modifications to the FDA-cleared hardware, software, design, or materials of these devices, without prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, where the modification does not create an undue risk in light of the public health emergency. Examples of circumstances where FDA currently believes a modification would not create such undue risk include:

1) Hardware, software, or design modifications implementing the capability for remote monitoring and remote manual adjustment of infusion parameters (i.e., manual adjustment of parameters by trained health care providers from outside an isolation unit to avoid unnecessary exposure). These modifications might include implementing the capability for remote monitoring and remote manual adjustment of infusion parameters via wired or wireless methods;
2) Modifications to increase battery capacity of the device;
3) Modifications to administration sets to increase the distance between the patient and health

care provider;

4) Modifications to the hardware and/or software to implement remote monitoring and adjustment of infusion parameters for multiple infusion pumps in a central location. This includes new hardware or software accessories for remote monitoring and remote manual adjustment of infusion parameters;
5) Modifications or additions to the hardware/software architectures to allow for increased remote monitoring and manual setting adjustment capability and availability to support additional indications described above. One example is the addition of wireless and/or Bluetooth capability; and
6) Additional hardware, software, design and material changes to an FDA-cleared infusion pump system accessory or component (e.g., material change to internal tubing) that enables an alternate accessory or component supplier to meet the established performance of the FDA-cleared system.

Additionally, FDA does not intend to object to firms making modifications or adding to the hardware/software architectures of these devices to allow for increased remote monitoring and setting adjustment capability/availability to support the types of additional indications described above. One example is the addition of wireless and/or Bluetooth capability. For any such changes, manufacturers should develop and implement appropriate cybersecurity controls to assure device cybersecurity and maintain device functionality and safety. FDA recommends firms refer to the following FDA guidance documents for consideration when pursuing hardware/software architecture changes:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices[13]
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices[14]
- Radio Frequency Wireless Technology in Medical Devices[15]
- Design Considerations and Pre-market Submission Recommendations for Interoperable Devices[16]

C. Distribution and Use of Infusion Pump System Accessory Devices Beyond Their Indicated Shelf Life and Duration of Use

Infusion pumps are designed to work as a system, which is comprised of various ancillary devices such as the tubing that connects the pump to the patient, filters, and manifolds. Accessory devices of an infusion pump system may include, but are not limited to, those in Table 2, when used in conjunction with an infusion system. These infusion pump system accessory devices might be labeled with specific durations of use and shelf life.

[13] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices.
[14] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0.
[15] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/radio-frequency-wireless-technology-medical-devices-guidance-industry-and-fda-staff.
[16] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-and-pre-market-submission-recommendations-interoperable-medical-devices.

FDA recognizes the urgent need during the COVID-19 public health emergency for infusion pump accessories due to increased use and demand, which has led to shortages in their availability. To help facilitate the availability of these accessories during the COVID-19 public health emergency, FDA does not intend to object to the distribution and use of infusion pump accessories beyond their indicated shelf life and/or duration of use that do not comply with the following regulatory requirements, where the infusion pump accessories do not create an undue risk in light of the public health emergency: prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81,[17] Registration and Listing requirements in 21 CFR 807, Quality System Regulation requirements in 21 CFR 820, reports of corrections and removals in 21 CFR Part 806, and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20. Examples of circumstances where FDA currently believes a change would not create such an undue risk:

- The devices are used according to healthcare institutional protocols; and
- The device is not distributed or used if there is evidence of malfunction or visible soiling.

An example where FDA currently believes a change would create such an undue risk would be the distribution or use of accessories with compromised sterile packaging.

D. Validation of Changes Made to Hardware, Software, Design, Materials, or Duration of Use

In designing, evaluating, and validating modifications made under this policy to hardware, software, design, materials, or duration of use, FDA recommends considering the following guidance documents and FDA recognized standards[18] for the specific device type, including (as applicable):

- Infusion Pumps Total Product Life Cycle[19]
- Intravascular Administration Sets Premarket Notification Submissions [510(k)][20]
- Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process'[21]
- IEC 60601-1: 2012: *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*
- IEC 60601-1-2: 2014: *Medical Electrical Equipment Part 1-2: General Requirements for*

[17] For further guidance on modifications that trigger the requirement that a manufacturer submit a new premarket notification (510(k)) to FDA, refer to "Deciding When to Submit a 510(k) for a Change to an Existing Device: Guidance for Industry and Food and Drug Administration Staff," https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device.

[18] For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. For more information regarding use of consensus standards in regulatory submissions, refer to FDA guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.

[19] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/infusion-pumps-total-product-life-cycle.

[20] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/intravascular-administration-sets-premarket-notification-submissions-510k.

[21] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and.

Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests

- IEC 60601-1-8: 2012: *Medical electrical equipment - Part 1-8: General Requirements for Basic Safety and Essential Performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
- IEC 60601-1-11: 2015: *Medical Electrical Equipment Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment*
- IEC 60601-1-12: 2014: *Medical electrical equipment - Part 1-12: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Intended for Use in the Emergency Medical Services Environment*
- Any other applicable collateral/particular standards in the IEC 60601-1: 2012 family
- IEC 62304: 2015: *Medical Device Software – Software Life Cycle Processes*
- AAMI TIR69: 2017: *Technical Information Report Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems*
- ANSI/IEEE C63.27: 2017: *American National Standard for Evaluation of Wireless Coexistence*
- ISO 10993-1: Fifth Edition 2018-08: *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
- ISO 594-1:1986; *Conical Fittings with A 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment - Part 1: General Requirements*
- ISO 594-2: 1998; *Conical Fittings with A 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment - Part 2: Lock Fittings*
- ISO 80369-6-: 2016: *Small Bore Connectors for Liquids and gases in Healthcare Applications -- Part 6: Connectors for Neuraxial Applications*
- ISO 8536-10: 2015: *Infusion Equipment for Medical Use - Part 10: Accessories for Fluid Lines for Single Use with Pressure Infusion Equipment*
- ISO 8536-10: 2015: *Infusion Equipment for Medical Use – Part 11: Infusion Filters for Single Use with Pressure Infusion Equipment*
- ISO 8536-4: 2010 (A1 2013) *Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed*
- ISO 8536-9: *Infusion Equipment for Medical Use - Part 9: Fluid Lines for Single Use with Pressure Infusion Equipment*

Recommendations regarding performance testing for infusion pump systems can be found in the FDA guidance document "Infusion Pump Total Product Life Cycle."[22] FDA continues to recommend a risk-based approach for the development of infusion pump systems and their accessories. Examples of hazardous situations that FDA recommends be addressed by manufacturers through risk control measures or mitigation strategies and verification and validation to avoid creating an undue risk

[22] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/infusion-pumps-total-product-life-cycle.

include:[23]

- Infusion delivery error,[24] including:
    - Over/under infusion (i.e., flow rate or bolus accuracy under all labeled operating conditions (e.g., temperature, humidity, back pressure, head heights) at the minimum and maximum flow rates or volumes);
    - Free flow; and
    - Occlusion detection.
- Air emboli,[25] including air-in-line detector and/or other mitigations.
- Fluid ingress: This should also consider the impact of cleaning as applicable to ensure continued safety and performance.
- Hazards related to power management, including:
    - Battery life; and
    - Impact of remote application on battery longevity.
- Hazardous situations associated with remote control, including:
    - Prioritization scheme of which controller has precedence;
    - Remote alarm communication to "secondary alarm" system;
    - Health care provider incorrectly perceives which pump or pump channel is being controlled;
    - Remote control does not interfere with local pump; and
    - Controller is synced to the wrong pump.
- Software- and cybersecurity-related hazards described in the FDA guidances and FDA-recognized voluntary consensus standards referenced in this section.

Manufacturers must document changes to their device in their device master record and change control records and make this information available to FDA, if requested, consistent with 21 CFR 820.30 and 21 CFR 820.180.

E. Labeling of Modified Devices

In addition, FDA recommends that the devices described above use labeling that helps users better understand the device modifications such as:

1) A clear description of the device's new indications or functions, and information on the device's performance and potential risks.
2) Adequate instructions for use for the intended user and indicated environment(s) of use. The labeling should highlight the differences in design compared to the unmodified, FDA-cleared version of the device, along with instructions for mitigating any known risks associated with

[23] The hazardous situations listed may not be applicable for all devices, such as software for a mechanical system. For such cases, FDA recommends that the manufacturer internally document if a hazard is not applicable.
[24] For the purposes of this guidance, infusion delivery error refers to the intended medication was selected, and delivery attempted, but failure to deliver within the right time, dose, volume, patient, or anatomical or physiologic site specifications.
[25] Different manufacturers often implement different solutions to mitigate the risk of air emboli. This is not limited to air in line detection, but can include other mitigations such as an air-in-line filter.

these differences. For example, design changes may impact existing labeling with MR compatibility information, such as device use in a specified MR environment under specific conditions of use (i.e., MR Conditional), and create undue risk in the absence of labeling that recommends against use in such an environment.

3) A clear distinction delineating FDA-cleared indications from those that are not FDA-cleared. In addition, FDA recommends the labeling include a general statement about changes that have not been cleared by FDA.

V. FDA's Intended Approach for EUAs for Infusion Pumps

Wherever possible, health care facilities should use FDA-cleared conventional/standard full-featured infusion pumps to treat patients who require continuous infusion therapy. However, to support the wider availability of devices for patients in need of infusion therapy in the United States for the duration of the public health emergency, FDA is interested in interacting with manufacturers of infusion devices that are not currently legally marketed in the U.S. as well as manufacturers who have not previously been engaged in medical device manufacturing with capabilities to increase supply of these devices. FDA will work interactively with these manufacturers through its EUA[26] process.

FDA would find it helpful if such manufacturers (whether foreign or domestic) send FDA the following information to CDRH-COVID19-InfusionPumps@fda.hhs.gov; FDA believes this information will be valuable in assessing whether the device is a good candidate for EUA authorization. FDA believes that companies may already have available information to help support an EUA request for infusion pumps, such as the information outlined below. FDA will expeditiously review this information, and other required information, to determine if an EUA can be issued.

1) For current infusion pump manufacturers whose product(s) are not currently marketed in the US, FDA recommends providing the following information:
    a. General information such as your contact information, name and place of business, email address, and contact information for a U.S. agent (if any), in addition to general information about the device such as the proprietary or brand name, model number, and marketing authorization in your country (or region);
    b. A copy of the product labeling;
    c. Whether the device currently has marketing authorization in another regulatory jurisdiction such as the European CE Mark, Australian Register of Therapeutic Goods (ARTG) Certificate of Inclusion, Health Canada Licence, or Ninsho certification in Japan. When providing this information, you should include a copy of the marketing authorization letter or certificate and also include any relevant corresponding information such as the certificate of conformity.
    d. Whether the device has been designed, evaluated, and validated considering the applicable performance testing, FDA guidance documents, and FDA-recognized

[26] For more information about FDA's EUA process, see the FDA guidance "Emergency Use Authorization of Medical Products and Related Authorities," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities.

standards identified in Section IV.D above;

e. Information in Section IV.D and listed below describing how the following hazardous situations were considered, risk control measures and mitigation strategies, and test reports for verification and validation:[27]
    i. Infusion delivery error, including:
        1. Over/under infusion (i.e., flow rate or bolus accuracy under all labeled operating conditions (e.g., temperature, humidity, back pressure, head heights) at the minimum and maximum flow rates or volumes);
        2. Free flow; and
        3. Occlusion detection.
    ii. Air emboli,[28] including air-in-line detector and/or other mitigations.
    iii. Fluid ingress: This should also consider the impact of cleaning as applicable to ensure continued safety and performance;
    iv. Hazards related to power management, including:
        1. Battery life; and
        2. Impact of remote application on battery longevity.
    v. Hazardous situations associated with remote control, including:
        1. Prioritization scheme of which controller has precedence;
        2. Remote alarm communication to "secondary alarm" system;
        3. Health care provider incorrectly perceives which pump or pump channel is being controlled;
        4. Remote control does not interfere with local pump; and
        5. Controller is synced to the wrong pump.
    vi. Software- and cybersecurity-related hazards described in the FDA guidances and FDA-recognized voluntary consensus standards referenced in Section IV.D. Labeling can be used to augment gaps in the cybersecurity plan and threat model, where appropriate. For such hazardous situations, FDA recommends inclusion of the cybersecurity threat model and unresolved software anomalies in the EUA.
f. Whether the device is manufactured in compliance with 21 CFR Part 820 or conformity with ISO 13485: *Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes,* or an equivalent quality system, and the manufacturer or importer has documentation of such.
g. Whether the device is designed with a power supply that is compatible with United States voltage, frequency, and plug type standards or is accompanied by an appropriate power supply adapter for use in the United States.

FDA will acknowledge receipt of the information provided, and intends to work interactively with these manufacturers to facilitate distribution of their products through an EUA in the United States

[27] The hazardous situations listed may not be applicable for all devices, such as software for a mechanical system. For such cases, FDA recommends that the manufacturer indicate if a hazard is not applicable.

[28] Different manufacturers often implement different solutions to mitigate the risk of air emboli. This is not limited to air in line detection, but can include other mitigations such as an air-in-line filter.

where issuing an EUA is appropriate.[29] In addition, where appropriate under the circumstances, FDA will notify the manufacturer that it does not intend to object to the distribution and use of the device while the manufacturer is preparing, and FDA is reviewing, the EUA request. Manufacturers who are unable to provide all the above information should engage with FDA through the pre-EUA process.

2) For manufacturers who have not previously been engaged in medical device manufacturing but with capabilities to increase supply of these devices:

   FDA welcomes the opportunity to work with manufacturers not previously engaged in medical device manufacturing with the interest and capability to manufacture infusion pump devices. This may include US manufacturers in other manufacturing sectors. These manufacturers should send an email to the address above and describe their proposed approach. FDA intends to work collaboratively with these manufacturers through its EUA process.

For any infusion pump device granted an EUA, FDA will include appropriate conditions of authorization in accordance with the mandatory conditions and optional conditions outlined in section 564(e)(1) of the FD&C Act. Although this is a case-by-case determination, based on current information and experience, we will likely include the following conditions:

- Appropriate conditions designed to ensure that health care professionals administering the device are informed—
  - that FDA has authorized the emergency use of the device;
  - of the significant known and potential benefits and risks of the emergency use of the device, and of the extent to which such benefit and risks are unknown; and
  - of the alternatives to the device that are available, and of their benefits and risks.
- Appropriate conditions designed to ensure that individuals to whom the device is administered are informed—
  - that FDA has authorized the emergency use of the device;
  - of the significant known and potential benefits and risks of the emergency use of the device, and of the extent to which such benefit and risks are unknown; and
  - of the option to accept or refuse use of the device, of the consequence, if any, of refusing administration of the device, and of the alternatives to the device that are available and of their benefits and risks.
- Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the device. FDA intends to include conditions that are consistent with those promulgated under 21 CFR Part 803.
- For manufacturers of the device, appropriate conditions concerning recordkeeping and reporting, including records access by FDA, with respect to emergency use of the device.

[29] For more information about FDA's EUA process, see the FDA guidance "Emergency Use Authorization of Medical Products and Related Authorities," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities.