



May 13, 2020

To Manufacturers of Infusion Pumps and Infusion Pump Accessories, Healthcare Providers, Hospital Purchasing Departments and Distributors, and Other Stakeholders:

The U.S. Food and Drug Administration (FDA) is issuing this Emergency Use Authorization (EUA) in response to concerns relating to the insufficient supply and availability of infusion pumps<sup>1</sup> and infusion pump accessories<sup>2</sup> for use by healthcare providers (HCPs) to treat patients with COVID-19 conditions<sup>3</sup> caused by the Coronavirus Disease 2019 (COVID-19) with the controlled infusion of medications, total parenteral nutrition (TPN), and/or other fluids.<sup>5</sup> This includes infusion pumps with remote monitoring or remote manual control features, infusion administration sets and other accessories with increased length that help maintain safe physical distance between HCPs and patients with confirmed or suspected COVID-19 to reduce HCP exposure to the virus that causes COVID-19.

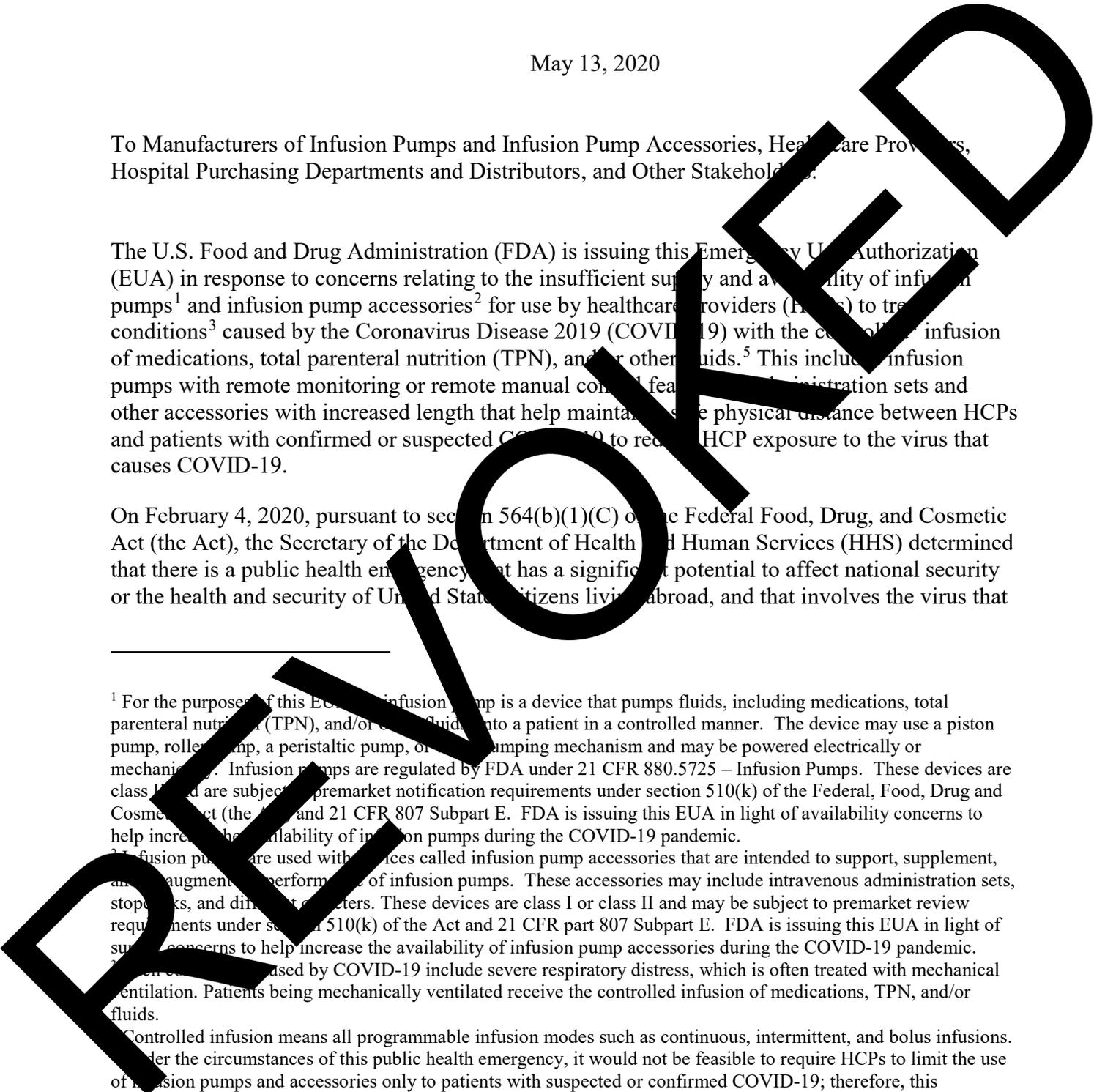
On February 4, 2020, pursuant to section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that

<sup>1</sup> For the purposes of this EUA, an infusion pump is a device that pumps fluids, including medications, total parenteral nutrition (TPN), and/or other fluids into a patient in a controlled manner. The device may use a piston pump, roller pump, a peristaltic pump, or a syringe pumping mechanism and may be powered electrically or mechanically. Infusion pumps are regulated by FDA under 21 CFR 880.5725 – Infusion Pumps. These devices are class II and are subject to premarket notification requirements under section 510(k) of the Federal Food, Drug and Cosmetic Act (the Act) and 21 CFR 807 Subpart E. FDA is issuing this EUA in light of availability concerns to help increase the availability of infusion pumps during the COVID-19 pandemic.

<sup>2</sup> Infusion pumps are used with devices called infusion pump accessories that are intended to support, supplement, and augment the performance of infusion pumps. These accessories may include intravenous administration sets, stopcocks, and drip chamber filters. These devices are class I or class II and may be subject to premarket review requirements under section 510(k) of the Act and 21 CFR part 807 Subpart E. FDA is issuing this EUA in light of supply concerns to help increase the availability of infusion pump accessories during the COVID-19 pandemic.

<sup>3</sup> Patients affected by COVID-19 include severe respiratory distress, which is often treated with mechanical ventilation. Patients being mechanically ventilated receive the controlled infusion of medications, TPN, and/or fluids.

<sup>5</sup> Controlled infusion means all programmable infusion modes such as continuous, intermittent, and bolus infusions. Under the circumstances of this public health emergency, it would not be feasible to require HCPs to limit the use of infusion pumps and accessories only to patients with suspected or confirmed COVID-19; therefore, this authorization does not restrict use to such patients.



causes COVID-19.<sup>6</sup> Pursuant to section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices subject to the terms of any authorization issued under that section.<sup>7</sup>

As discussed further below, I have concluded that an infusion pump or infusion pump accessory meeting the criteria for safety, performance, and labeling set forth in Section II meets that the criteria for issuance of an EUA in section 564(c) of the Act are met.

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act are met, I am authorizing the emergency use of the infusion pump and infusion pump accessories that FDA confirms meet the criteria for safety, performance, and labeling set forth in Section II and pursuant to the Conditions of Authorization (Section III) of this letter (referred to in this letter as “authorized infusion pumps and infusion pump accessories”). Infusion pump and infusion pump accessories that have been authorized will be added to this letter of authorization in Appendix A.

### **I. Criteria for Issuance of Authorization**

I have concluded that the emergency use of the authorized infusion pumps and infusion pump accessories as described in the Scope of Authorization (Section II) of this letter for use by HCPs to treat conditions caused by COVID-19 with the controlled infusion of medications, TPN, and/or other fluids meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that authorized infusion pumps and infusion pump accessories may be effective for use by HCPs to treat conditions caused by COVID-19 with the controlled infusion of medications, TPN, and/or other fluids, and that the known and potential benefits of such products, for such use outweigh the known and potential risks of such products; and,
3. There is no adequate, approved, and available alternative to the emergency use of the authorized infusion pumps and infusion pump accessories to treat patients during the COVID-

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<sup>6</sup> U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020).

<sup>7</sup> U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3. 85 FR 17335 (March 27, 2020).

19 pandemic.<sup>8,9</sup>

## II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of authorized infusion pumps and infusion pump accessories by HCPs to treat conditions caused by COVID-19 with the controlled infusion of medications, TPN, and/or other fluids.<sup>10</sup>

### Infusion Pumps and Infusion Pump Accessories Eligible for Authorization under this EUA

The infusion pumps and infusion pump accessories that are eligible for inclusion under this EUA are those that are not currently cleared or approved in the U.S. or that are currently cleared in the U.S. but a modification is made to the device that would trigger the requirement that a manufacturer submit a new premarket notification (510(k)) to FDA.<sup>11</sup> The products that are currently marketed in the U.S. fall under the regulations and within the device types listed in Table 1 (infusion pumps) or Table 2 (infusion pump accessories).

Table 1. Infusion Pumps

Classification Regulation	Device Type	Product Code	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 Patient Software	PHC	II

<sup>8</sup> No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

<sup>9</sup> As COVID-19 continues to expand globally, the supply chain for infusion pumps and infusion pump accessories that meet FDA regulatory requirements has been substantially stressed, with shortages already being observed in United States healthcare institutions, with demand exceeding the available supply. These infusion pumps and infusion pump accessories are integral to treat patients that require the controlled infusion of medications, TPN, and other fluids, including those undergoing mechanical ventilation due to severe respiratory distress. Under the circumstances of this public health emergency, nationwide shortages are expected, and FDA has taken steps to address the observed and anticipated shortages of infusion pumps and infusion pump accessories by issuing FDA's enforcement policy (see footnote 11) for infusion pumps and infusion pump accessories. Based on the observed and expected shortages, as discussed above, the Agency continues to be concerned that there are not sufficient quantities of infusion pumps and infusion pump accessories available to meet the needs of the United States healthcare system.

<sup>10</sup> Under the circumstances of this public health emergency, it would not be feasible to require HCPs to limit the use of infusion pumps and accessories only to patients with suspected or confirmed COVID-19; therefore, this authorization does not restrict use to such patients.

<sup>11</sup> For further discussion of FDA's enforcement policy for infusion pumps and infusion pump accessories during the COVID-19 public health emergency, please see FDA's guidance, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-infusion-pumps-and-accessories-during-coronavirus-disease-2019-covid-19-public>.

**Table 2. Infusion Pump Accessories**

Classification Regulation	Device Type	Product Code	Class
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	PI	II
21 CFR 880.5420	Pressure infusor for I.V. bags	PLD	II
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	FPP	II
21 CFR 880.5440	Check valve, retrograde flow (in-line)	PL	II
21 CFR 880.5440	Administrations sets with neuraxial connectors	PV	II
21 CFR 880.5440	Neuraxial administration set - intrathecal delivery	PYR	II
21 CFR 880.5445	Intravascular administration set with automated air detection system	OKL	II
21 CFR 880.5570	Non-corin (Huber) needles	PTI	II
21 CFR 880.5725	Electronic intravascular infusion controller	LDR	II
21 CFR 880.5970	Therapeutic intravascular catheter, long-term greater than 30 days	LJS	II
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

Enteral feeding pumps, elastomeric infusion pumps, and insulin pumps are not eligible to be added to this EUA. Moreover, devices intended solely for sustained infusion therapy provided through a physiological closed loop or similarly developed closed loop system are also not eligible to be added to this EUA.

**Authorization Process**

To be authorized, infusion pumps and infusion pump accessories must be confirmed by FDA to meet the applicable criteria for safety, performance, and labeling set forth in Section II. FDA will add an authorized infusion pump or infusion pump accessory to the list of authorized products in Appendix A upon submission of a request from the manufacturer as described below and after confirmation by FDA that the applicable criteria have been met, and pursuant to the Conditions of Authorization in this EUA. A manufacturer may request the inclusion of any

infusion pump or infusion pump accessory by submitting a request to [CDRH-COVID19-InfusionPumps@fda.hhs.gov](mailto:CDRH-COVID19-InfusionPumps@fda.hhs.gov) that includes the following information:

- 1) 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 information as specified in 3) below (if any).
- 2) A copy of the product labeling.
- 3) 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 Japan Pharmaceutical and Medical Device (PMDA) Ninsho approval (including certification number, if available).
- 4) Whether the device is manufactured in compliance with a quality system such as 21 CFR Part 820 or 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.
- 5) Information sufficient to demonstrate that the device meets the applicable criteria below.

### Criteria for Safety, Performance, and Labeling

To be authorized, infusion pumps and infusion pump accessories must be confirmed by FDA to meet the applicable criteria for safety, performance, and labeling set forth below. The standards and hazards listed below have been specifically identified to have an impact on infusion pump and infusion pump accessory performance in support of the treatment of patients during the COVID-19 pandemic. FDA will add an authorized infusion pump or infusion pump accessory to the list of authorized products in Appendix A upon submission of a request from the manufacturer as described in Section 10.1 and after confirmation by FDA that the applicable safety, performance, and labeling criteria have been met, and pursuant to the Conditions of Authorization in the EUA.

### Declarations of Conformity

In order to demonstrate that the infusion pump or infusion pump accessory has been designed, evaluated, and verified in accordance with and meets the applicable FDA-recognized standards, manufacturers shall provide declarations of conformity with the following standards, as applicable to the device:

- 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 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 Emergency Medical Services Environment*
- Any other applicable collateral/particular standards in the IEC 60601-1-11/12 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*

In addition, the infusion pump or infusion pump accessory shall meet, and manufacturers shall provide declarations of conformity with, the following medical standards, as applicable to the device:

- 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 80269-6-: 2015: *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 8536-11: 2015: *Infusion Equipment for Medical Use – Part 11: Infusion Filters for Single Use with Pressure Infusion Equipment*
- ISO 8536-4: 2010 (2013): *Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed*
- ISO 8536-9: 2015: *Infusion Equipment for Medical Use - Part 9: Fluid Lines for Single Use with Pressure Infusion Equipment*

### ***Risk Management Activities***

Manufacturers shall provide information describing how the following hazardous situations were considered for the infusion pump or infusion pump accessory,<sup>12</sup> including risk control measures and mitigation strategies and test reports for verification and validation:<sup>13</sup>

### ***Infusion Pump Performance Hazards:***

- Infusion delivery error, 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,<sup>14</sup> including air-in-line detector and/or other mitigations;
- Fluid ingress: This must also consider the impact of cleaning as applicable to ensure continued safety and performance;
- For sterile devices, you shall describe the sterilization process used (see recommendations outlined in the FDA guidance [Submission and Review of Sterility Information in Premarket Notification \(510\(k\)\) Submissions for Devices Labeled as Sterile](#);<sup>15</sup> and,
- Hazards related to power management, including:
  - Battery life
  - If the device uses electrical power (as opposed to strictly relying on battery power), you shall describe whether the device is designed with a power supply that is compatible with United States voltage, frequency, and plug type standards or is alternatively accompanied by an appropriate power supply adapter for use in the United States.

### ***Remote Monitoring and Remote Manual Control Hazards (as applicable):***

- Prioritization of remote controller has precedence;
- Remote alarm communication to “secondary alarm” system;
- Healthcare provider incorrectly perceives which pump or pump channel is being controlled;
- Power management (e.g., impact of remote use on battery longevity);
- Remote manual control does not interfere with local pump; and,

<sup>12</sup> The risk management activities shall be considered at the system level when appropriate. This would include the pump administration sets, infusion management software, drug library, and other accessories necessary for the pump to be used in its intended use safely.

The hazardous situations listed may not be applicable for all devices, such as software for a mechanical system. For such cases, the manufacturer is to indicate if a hazard is not applicable.

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.

<sup>15</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled>.

- Controller is synced to the wrong pump.

***Software and Cybersecurity Hazards (as applicable):***

Manufacturers shall develop and implement appropriate software- and cybersecurity-controls to assure device cybersecurity and maintain device functionality and safety. These controls shall be provided in the request. At a minimum, you shall identify the Level of Concern for your software and, for Moderate and Major Levels of Concern, provide a description of the unresolved anomalies associated with your device software as described in the [Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices)<sup>16</sup> as well as a threat model as described in the FDA guidance [Content of Premarket Submissions for Management of Cybersecurity in Medical Devices](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0).<sup>17</sup>

***Device Specifications and Instructions for Infusion Pumps and Infusion Pump Accessories***

Manufacturers of infusion pumps and infusion pump accessories shall provide the following information in their instructions for use as applicable:

- Accuracy specifications over the range of selectable flow rates and bolus volumes. For example, time period over which accuracy is specified, time to reach steady-state flow accuracy, and effect of infusion rate changes on bolus accuracy.
- Factors that may affect flow accuracy such as ambient temperature, fluid temperature, pressure (e.g., head-height, backpressure, atmospheric pressure), fluid viscosity, and/or changes in flow rate or bolus delivery (e.g., with titration medications).
- Description of all alarm or information messages including alarm limits and ranges, and recommended actions when alarms or information messages are provided.
- Default settings for alarms, sensors (e.g., air-in-line detection), and other adjustable parameters.
- Selectable flow rates and profiles.
- An identification of any dedicated administration set, specifications, and/or specific models of infusion sets that are intended for use with the infusion pump.
- Method(s) to be used to confirm that the device operates within calibration for all relevant delivery features.
- Instructions for handling the device during power outages.
- Instructions for appropriate home use of the device, as applicable.<sup>18</sup>
- Warning statements regarding the safety of use during diagnostic procedures, such as magnetic resonance imaging, x-ray, computed tomography, or ultrasound.

<sup>16</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices>.

<sup>17</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0>.

<sup>18</sup> For more information on FDA’s labeling recommendations regarding the home use of devices see the FDA guidance document “Design Considerations for Devices Intended for Home Use,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-devices-intended-home-use>.

- Electromagnetic compatibility (EMC) information consistent with or equivalent to the relevant voluntary consensus standard (e.g., IEC 60601-1-2).
- For devices with radiofrequency wireless technology capabilities, information about the RF wireless technology intended to be used.<sup>19</sup>

### ***Reprocessing and Shelf-life Information***

As applicable, manufacturers of infusion pumps and infusion pump accessories shall provide the following information and instructions regarding device reprocessing in the instructions for use:

- Instructions on how to clean and disinfect reusable infusion pumps and accessories. For home use devices, instructions using readily available cleaning and disinfection supplies for hygienic maintenance.
- Information regarding device shelf-life.

### ***Labeling Requirements***

The manufacturer must include in the instructions for use, the following information:

- Device specifications;
- Information regarding alarms;
- Device reprocessing and shelf life information, and
- Other instructions described above as applicable.

The manufacturer must also have Fact Sheets as outlined below.

### **Authorized Infusion Pumps and Infusion Pump Accessories**

Infusion pumps and infusion pump accessories are authorized under this EUA and listed in Appendix A when FDA confirms they meet the applicable criteria for safety, performance, and labeling set forth in this section (Section II) and the terms and conditions of this Authorization have been met. Authorized infusion pumps and infusion pump accessories are authorized to be manufactured, distributed, and used for treatment of patients under this EUA, despite the fact that such products do not meet certain requirements otherwise required by applicable federal law. These products are not approved or cleared by FDA for such use.

Authorized infusion pumps and infusion pump accessories must be accompanied by labeling that includes information specified in this section above. In addition, the authorized products must be accompanied by the following information pertaining to the emergency use, which are authorized to be made available to HCPs and patients:

Fact Sheet for Healthcare Providers: Emergency Use of Infusion Pumps and Infusion Pump Accessories During the COVID-19 Pandemic

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<sup>19</sup> For example, this could include specific information about the technology (e.g., IEEE 802.11 b), the frequency of operation and range, quality of service required for the claimed functions, data integrity, recommended security measures for the RF wireless technology (e.g., WPA2), coexistence and any limitations (e.g., distance between RF devices, EMC limitations).

- Fact Sheet for Patients: Emergency Use of Infusion Pumps and Infusion Pump Accessories During the COVID-19 Pandemic

The manufacturer’s labeling, which includes instructions for use specific to the emergency use of the product in response to the COVID-19 pandemic and the two fact sheets, are referred to as “authorized labeling.”

FDA may remove an authorized infusion pump or infusion pump accessory from Appendix A of this EUA if FDA has reason to believe that the product no longer meets the Scope of Authorization (Section II) or any of the Conditions of Authorization (Section IV). FDA will provide the manufacturer 24 hours advance notice of such removal, and will be available to consult with the manufacturer to resolve the issue(s) that led to removal of the device(s) from the EUA. Devices that are removed from the EUA will appear on a list maintained on FDA’s website and may not be used unless or until they are added back on this EUA, or are otherwise approved, cleared, or authorized by FDA.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized infusion pumps and infusion pump accessories, when used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such products.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized infusion pumps and infusion pump accessories may be effective in treating patients during the COVID-19 pandemic, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the comparisons described in Section I above, and concludes that the authorized infusion pumps and infusion pump accessories, when used to treat conditions caused by COVID-19 (as described in the Scope of Authorization of this letter (Section II)), meet the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of authorized infusion pumps and infusion pump accessories under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS’s determination under section 564(d)(3)(C) of the Act described above and the Secretary of HHS’s corresponding declaration under section 564(b)(1) of the Act, infusion pumps and infusion pump accessories that are determined to meet the applicable criteria for safety, performance, and labeling set forth in this section (Section II) are authorized to be used and distributed as set forth in this EUA.

## II. Waiver of Certain FDA Requirements

For authorized infusion pumps and infusion pump accessories during the duration of this EUA, I am waiving good manufacturing practices otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulations under the Act, including the quality system

requirements under 21 CFR Part 820 and other requirements established under section 520(f)(1) of the Act.

#### IV. Conditions of Authorization

Pursuant to section 564(e) of the Act, I am establishing the following conditions on this authorization:

##### Manufacturers of Authorized Products

- A. Manufacturers must comply with labeling requirements under 21 CFR 801 Subpart A (general labeling provisions) and 21 CFR 801.109 (labeling for prescription devices), as well as those described in the Scope of Authorization (Section II). Compliance with unique device identification regulations (see Subpart B of 21 CFR Part 801) is not required under this EUA.
- B. Manufacturers will have a process in place to collect information on the performance of their product and for reporting adverse events in accordance with 21 CFR Part 803. Adverse events of which the manufacturer becomes aware will be reported to FDA. Adverse events related to an authorized use of an authorized product will be reported in a manner to distinguish them from events related to FDA-cleared uses of the products.
- C. Manufacturers will include in the instructions for use instructions for recommended cleaning and/or disinfection materials and processes, as applicable, for their authorized product(s).
- D. Manufacturers will notify FDA of any authorized distributor(s) of the product, including the name, address, and phone number of any authorized distributor(s), and provide authorized distributor(s) with a copy of this EUA.

##### Manufacturers and Authorized Distributors<sup>20</sup> of Authorized Products

- E. Manufacturers and authorized distributors will make infusion pumps and infusion pump accessories available with the authorized labeling, as described in the Scope of Authorization (Section II) of this letter.
- F. Manufacturers and authorized distributors will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.
- G. Manufacturers and authorized distributors will instruct healthcare facilities to notify them if a healthcare facility intends to use any FDA-cleared infusion pump or infusion pump accessory that was distributed prior to the addition of such product to the EUA for use under this authorization. Manufacturers and authorized distributors will make available the authorized labeling, including Fact Sheets to each healthcare facility who notifies the manufacturer or authorized distributor that they intend to use the products under this EUA.

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<sup>20</sup> “Authorized Distributor(s)” are identified by the manufacturer in an EUA submission as an entity allowed to distribute the device.

- H. Through a process of inventory control, manufacturers and authorized distributors will maintain records of the entities to which they distribute the infusion pumps and infusion pump accessories and the numbers of each such product they distribute. Manufacturers and authorized distributors will maintain distribution records for all devices under this EUA, including for both new and existing customers.
- I. Manufacturers and authorized distributors are authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.

**Conditions Related to Printed Materials, Advertising and Promotion**

- J. All descriptive printed matter, including advertising and promotional materials relating to the use of the authorized infusion pumps and infusion pump accessories, shall be consistent with the authorized labeling, as well as the terms set forth in the EUA and the applicable requirements set forth in the Act and FDA regulations.
- K. No descriptive printed matter, including advertising and promotional materials relating to the use of the authorized infusion pumps and infusion pump accessories, shall represent or suggest that such products are safe or effective for the prevention or treatment of patients during the COVID-19 pandemic.
- L. All descriptive printed matter, including advertising and promotional materials relating to the use of the authorized infusion pumps and infusion pump accessories clearly and conspicuously shall state that:
- This infusion pump or infusion pump accessory (as applicable) has not been FDA-cleared or approved for use by HCPs to treat conditions caused by COVID-19 with the controlled infusion of medications, TPN, and/or other fluids;
  - This infusion pump or infusion pump accessory (as applicable) has been authorized for emergency use by FDA under an EUA;
  - This infusion pump or infusion pump accessory (as applicable) is only authorized for the emergency use of the device under the declaration that circumstances exist justifying the authorization under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

**V. Duration of Authorization**

This EUA is effective until the declaration that circumstances exist justifying the authorization of the emergency use of medical devices is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

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RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration

Enclosure

**REVOKED**