February 3, 2025

First Medical Source, LLC
Mark Shal
CEO
28581 Springfield Drive
Laguna Niguel, California 92677

Re: K240624
Trade/Device Name: InfuLife
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: MEB

Dear Mark Shal:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated 11/05/2024. Specifically, FDA is updating the 510(k) Summary to state that the subject device is for ambulatory use as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jake Lindstrom, OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices, 301-796-5716, jake.lindstrom@fda.hhs.gov.

Sincerely,

Juliane C. Lessard -S

Juliane C. Lessard, Ph.D.
Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

November 5, 2024

First Medical Source, LLC
Mark Shal
CEO
28581 Springfield Drive
Laguna Niguel, California 92677

Re: K240624
Trade/Device Name: InfuLife
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: MEB
Dated: October 3, 2024
Received: October 3, 2024

Dear Mark Shal:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jake K. Lindstrom -S

Jake Lindstrom, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K246024

Device Name
InfuLife

Indications for Use *(Describe)*
InfuLife is a single-use, sterile, disposable elastomeric infusion pump intended for continuous and/or intermittent infusion of medications for general infusion at home, in a hospital, or in alternate sites. InfuLife is indicated for delivery of antibiotics, chemotherapy, and pain management, as directed by a physician or licensed healthcare professional. Routes of administration include intravenous, intra-arterial, subcutaneous, intramuscular, and epidural. Additionally, InfuLife is indicated for continuous and/or intermittent delivery of medication, such as local anesthetics or narcotics, to surgical wound sites and/or proximity to nerves for preoperative, perioperative, and postoperative regional anesthesia and pain management. InfuLife is intended for use by physicians, clinicians, pharmacists, and other licensed healthcare professionals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K240624 510(k) Summary

This 510(k) Summary of safety and effectiveness information is prepared in accordance with the requirements of CFR Part 807.92.

Submitter Information

510(k) Sponsor	First Medical Source, LLC 28581 Springfield Drive Laguna Niguel CA 92677 United States
Contact Person(s)	Dr. Mark Shal CEO Phone: (949) 637-5222 Email: mshal@firstmedicalsource.com
Date Prepared	January 30, 2025

Proposed Device: K240624

Common/Usual Name:	Elastomeric Infusion pump
Trade/Proprietary Name:	InfuLife
Classification Name:	Pump, Infusion, Elastomeric
Device Classification:	880.5725
Product Code:	MEB, FRN
Class:	II
Device Panel:	General Hospital

Predicate Device: K151650

Common/Usual Name:	Elastomeric Infusion pump
Trade/Proprietary Name:	SMARTeZ elastomeric infusion pump
Classification Name:	Pump, Infusion, Elastomeric
Device Classification:	880.5725
Product Code:	MEB
Class:	II
Device Panel:	General Hospital

Device Description

InfuLife is a non-electrically driven, portable fixed flow rate infusion pump. The fluid is pushed forward by the pressure of the elastomeric bladder. The flow rate of the device is predetermined by the manufacturer using Hagen-Poiseuille theory, which calculates the volumetric flow rate of a fluid with certain viscosity passing through a cylindrical pipe with a known diameter, at a given pressure and temperature.

Indications for Use

InfuLife is a single-use, sterile, disposable elastomeric infusion pump intended for continuous and/or intermittent infusion of medications for general infusion at home, in a hospital, or in alternate sites.

InfuLife is indicated for delivery of antibiotics, chemotherapy, and pain management, as directed by a physician or licensed healthcare professional. Routes of administration include intravenous, intra-arterial, subcutaneous, intramuscular, and epidural. Additionally, InfuLife is indicated for continuous and/or intermittent delivery of medication, such as local anesthetics or narcotics, to surgical wound sites and/or proximity to nerves for preoperative, perioperative, and postoperative regional anesthesia and pain management.

InfuLife is intended for use by physicians, clinicians, pharmacists, and other licensed healthcare professionals.

InfuLife is intended for use by adult patients, and children weighing more than 20 Kg.

Contraindications

InfuLife is contraindicated for intra-articular infusion of anesthetics and for infusion of blood and blood products, infusion of insulin, infusion of critical or life-supporting medications, infusion of any solution that is not compatible with the fluid path materials; and use in ambulatory regimens by patients not capable of self-administering their therapy or not under the care of a responsible individual.

Residual Risks

InfuLife is contraindicated for use on neonates, infants, and children weighing less than 20 Kg due to potential exposure to EO residuals.

Substantial Equivalence Discussion

The table below compares the characteristics of the subject device to the predicate device.

Device & Predicate Device(s):	K240624	K151650	Comments
General Device Characteristics			
Classification Regulation	880.5725	Same	
Product Code	MEB	Same	

Intended Use	General non-life sustaining infusion	Same	
Indications for Use	InfuLife is a single-use, sterile, disposable elastomeric infusion pump intended for continuous and/or intermittent infusion of medications for general infusion at home, in a hospital, or in alternate sites. InfuLife is indicated for delivery of antibiotics, chemotherapy, and pain management, as directed by a physician or licensed healthcare professional. Routes of administration include intravenous, intra-arterial, subcutaneous, intramuscular, and epidural. Additionally, InfuLife is indicated for continuous and/or intermittent delivery of medication, such as local anesthetics or narcotics, to surgical wound sites and/or proximity to nerves for preoperative, perioperative, and postoperative regional anesthesia and pain management. InfuLife is intended for use by physicians, clinicians, pharmacists, and other licensed healthcare professionals.	The SMARTez Elastomeric Infusion Pump is intended for continuous and/or intermittent infusion of medications for general infusion use, including antibiotic delivery, chemotherapy and pain management. Routes of administration include the following: intravenous, intra-arterial, subcutaneous, intramuscular and epidural. The device is also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intra-operative, perineural or percutaneous.	The indications for use, routes of administration, and user base is the same.
Operating Principle	Pressure created by a silicon reservoir pushes a fluid through a tubing which integrates a calibrated flow restrictor.	Same	
Bolus	N/A		The sponsor notes that a dedicated bolus cord will be provided in a later submission update.

<table>
<tr>
<td>Weight and Dimensions</td>
<td>
<table>
<tr><th>Pump size</th><th>Length pump (inch)</th><th>Length administration tube (inch)</th><th>Length flow control tube (inch)</th><th>Weight (g)</th></tr>
<tr><td>Small</td><td>3.94</td><td>35.43</td><td>5.90-15.75</td><td>53</td></tr>
<tr><td>Medium</td><td>5.12</td><td>35.43</td><td>5.90-15.75</td><td>61</td></tr>
<tr><td>Large</td><td>6.30</td><td>35.43</td><td>5.90-15.75</td><td>73</td></tr>
<tr><td>XLarge</td><td>7.48</td><td>35.43</td><td>5.90-15.75</td><td>87</td></tr>
<tr><td>Small</td><td>3.54</td><td>42.68</td><td>2.16-15.12</td><td>33</td></tr>
<tr><td>Medium</td><td>4.72</td><td>42.68</td><td>2.16-15.12</td><td>41</td></tr>
<tr><td>Large</td><td>5.90</td><td>42.68</td><td>2.16-15.12</td><td>53</td></tr>
<tr><td>XLarge</td><td>5.90</td><td>42.68</td><td>2.16-15.12</td><td>67</td></tr>
<tr><td>Small</td><td>3.0</td><td>35.0</td><td>5.12-17.72</td><td>44</td></tr>
<tr><td>Medium</td><td>3.0</td><td>35.0</td><td>5.12-17.72</td><td>46</td></tr>
<tr><td>Large</td><td>3.0</td><td>35.0</td><td>5.12-17.72</td><td>47</td></tr>
</table>
InfuLife weight and dimensions are highlighted in yellow
</td>
<td>
<table>
<tr><th>Pump size</th><th>Length pump (inch)</th><th>Length administration tube (inch)</th><th>Length flow control tube (inch)</th><th>Weight (g)</th></tr>
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<tr><td>XLarge</td><td>7.48</td><td>35.43</td><td>5.90-15.75</td><td>87</td></tr>
</table>
</td>
<td>1.Similar. Any size and weight differences between the subject and predicate device are negligible.</td>
</tr>
<tr>
<td>Flow Accuracy and Rate</td>
<td>
<table>
<tr><th>Nominal Fill Volume (ml)</th><th>Max / Min Volume (ml)</th><th>Residual Volume (ml)</th></tr>
<tr><td>100 ml - 125 ml
270 ml
400 ml</td><td>+ 5 ml / - 5 ml
+ 10 ml / - 10 ml
+ 5 ml / - 10 ml</td><td>5.0 ml</td></tr>
</table>
<table>
<tr><td>Low Flow pump Rates</td><td>0.5 to 10 mL/hr</td></tr>
<tr><td>High Flow Pumps Rates</td><td>50 to 250 mL/hr</td></tr>
</table>
Accuracy: Flow within ± 12% nominal fill volume
</td>
<td>
Table 13-3. List of short infusion time articles with 2 units per blister pack
<table>
<tr><th>Type</th><th>Designation</th><th>Nominal filling volume (ml)</th><th>Nominal flow rate (ml/h)</th><th>Nominal infusion time (h)</th><th>Article Number (REF)</th></tr>
<tr><td rowspan="10">Short Infusion Time Articles</td><td>SMARTez 100-200-30m</td><td>100</td><td>200</td><td>0.5</td><td>481012</td></tr>
<tr><td>SMARTez 250-500-30m</td><td>250</td><td>500</td><td>0.5</td><td>481022</td></tr>
<tr><td>SMARTez 50 -50 -60m</td><td>50</td><td>50</td><td>1</td><td>481032</td></tr>
<tr><td>SMARTez 100-100-60m</td><td>100</td><td>100</td><td>1</td><td>481042</td></tr>
<tr><td>SMARTez 250-250-60m</td><td>250</td><td>250</td><td>1</td><td>481052</td></tr>
<tr><td>SMARTez 250-175-90m</td><td>250</td><td>175</td><td>1.5</td><td>481062</td></tr>
<tr><td>SMARTez 100-50-120m</td><td>100</td><td>50</td><td>2</td><td>481092</td></tr>
<tr><td>SMARTez 200-100-120m</td><td>200</td><td>100</td><td>2</td><td>481112</td></tr>
<tr><td>SMARTez 250-100-150m</td><td>250</td><td>100</td><td>2.5</td><td>481122</td></tr>
<tr><td>SMARTez 250-125-120m</td><td>250</td><td>125</td><td>2</td><td>481132</td></tr>
<tr><td>SMARTez 200-200-60m</td><td>200</td><td>200</td><td>1</td><td>481142</td></tr>
</table>
Table 13-2. List of long infusion time, chemotherapy, and articles with nominal volume ≥400 (1 unit per blister pack)
<table>
<tr><th>Type</th><th>Designation</th><th>Nominal volume (ml)</th><th>Nominal flow rate (ml/h)</th><th>Nominal time (h)</th><th>Article Number (REF)</th></tr>
<tr><td rowspan="25">Long Infusion Time Articles</td><td>SMARTez 60-5-12h</td><td>60</td><td>5</td><td>12</td><td>480011</td></tr>
<tr><td>SMARTez 80-5-16h</td><td>80</td><td>5</td><td>16</td><td>480021</td></tr>
<tr><td>SMARTez 125-5-25h</td><td>125</td><td>5</td><td>25</td><td>480031</td></tr>
<tr><td>SMARTez 270-10-27h</td><td>270</td><td>10</td><td>27</td><td>480041</td></tr>
<tr><td>SMARTez 60-2-30h</td><td>60</td><td>2</td><td>30</td><td>480051</td></tr>
<tr><td>SMARTez120-4-30h</td><td>120</td><td>4</td><td>30</td><td>480061</td></tr>
<tr><td>SMARTez 400-10-40h</td><td>400</td><td>10</td><td>40</td><td>480071</td></tr>
<tr><td>SMARTez 100-2-50h</td><td>100</td><td>2</td><td>50</td><td>480081</td></tr>
<tr><td>SMARTez 270-5-54h</td><td>270</td><td>5</td><td>54</td><td>480091</td></tr>
<tr><td>SMARTez 120-2-60h</td><td>120</td><td>2</td><td>60</td><td>480101</td></tr>
<tr><td>SMARTez 400-5-80h</td><td>400</td><td>5</td><td>80</td><td>480111</td></tr>
<tr><td>SMARTez 100-1.5-67h</td><td>100</td><td>1.5</td><td>67</td><td>480121</td></tr>
<tr><td>SMARTez 270-4-68h</td><td>270</td><td>4</td><td>68</td><td>480131</td></tr>
<tr><td>SMARTez 400-4-100h</td><td>400</td><td>4</td><td>100</td><td>480141</td></tr>
<tr><td>SMARTez 65-0.5-130h</td><td>65</td><td>0.5</td><td>130</td><td>480151</td></tr>
<tr><td>SMARTez 270-2-135h</td><td>270</td><td>2</td><td>135</td><td>480161</td></tr>
<tr><td>SMARTez 300-2-150h</td><td>300</td><td>2</td><td>150</td><td>480171</td></tr>
<tr><td>SMARTez 100 -0.5-200h</td><td>100</td><td>0.5</td><td>200</td><td>480181</td></tr>
<tr><td>SMARTez 270-1-270h</td><td>270</td><td>1</td><td>270</td><td>480191</td></tr>
<tr><td rowspan="5">Chemo-therapy Articles</td><td>SMARTez C100-2-50h</td><td>100</td><td>2</td><td>50</td><td>484011</td></tr>
<tr><td>SMARTez C270-2-135h</td><td>270</td><td>2</td><td>135</td><td>484021</td></tr>
<tr><td>SMARTez C120-4-30h</td><td>120</td><td>4</td><td>30</td><td>484031</td></tr>
<tr><td>SMARTez C270-5-54h</td><td>270</td><td>5</td><td>54</td><td>484041</td></tr>
<tr><td>SMARTez C270-10-27h</td><td>270</td><td>10</td><td>27</td><td>484051</td></tr>
<tr><td rowspan="3">Short Infusion Time Articles</td><td>SMARTez 400-200-120m</td><td>400</td><td>200</td><td>2</td><td>481071</td></tr>
<tr><td>SMARTez 500-250-120m</td><td>500</td><td>250</td><td>2</td><td>481081</td></tr>
<tr><td>SMARTez 400-100-240m</td><td>400</td><td>100</td><td>4</td><td>481101</td></tr>
</table>
Accuracy: Flow within ± 15% of the labelled flow rate.
</td>
<td>2.The flow rates and flow accuracies of the subject device is encompassed within the predicate device.</td>
</tr>
<tr>
<td>Material</td>
<td>
<table>
<tr><th>Item #</th><th>Material</th><th>Fluid Path</th><th>Biocompatibility History and supporting materials</th></tr>
<tr><td>1</td><td>Silicone, QP1-40/50, mfg. Dow Corning</td><td>Yes</td><td>Same material as K151650</td></tr>
<tr><td>2</td><td>ABS, Cycolac HMG94MD-1H1000, mfg. Sabic Innovative Plastics</td><td>Yes</td><td>Same material as K052117 and K081905</td></tr>
<tr><td>3</td><td>ASA, MABS, Silicone</td><td>Yes</td><td>Same material as K981816</td></tr>
<tr><td>4</td><td>ABS Terlux 2802</td><td>Yes</td><td>Material used in K855039 and K852605</td></tr>
<tr><td>5</td><td>Polypropylene, Purell HP371P, +1% mstrbtch VIBA PE White 10040</td><td>Yes</td><td>Material used in K855039 and K852605</td></tr>
<tr><td>6</td><td>PVC, Unichem 7877G-015, mfg. Colorite Polymers</td><td>Yes</td><td>Same material as K981816</td></tr>
<tr><td>7</td><td>Acrylic, DRG-100 Filtertek</td><td rowspan="2">Yes</td><td rowspan="2">Same material as K052117 and K081905</td></tr>
<tr><td>8</td><td>Polyethersulfone Gelman</td></tr>
<tr><td>9</td><td>PTFE, Goretex L12126 Gore</td><td></td><td></td></tr>
<tr><td>10</td><td>Soda Lime Glass, 8350 AR-Glas</td><td>Yes</td><td>Same material as K052117 & K081905</td></tr>
<tr><td>11</td><td>Colorite Polymers Flexchem 6551-02 Vinyl Compound</td><td>Yes</td><td>Same material as K981816</td></tr>
</table>
</td>
<td></td>
<td>3.The material composition of the predicate device is not provided, however, it is not needed as the appropriate biocompatibility endpoint testing will be reviewed for subject device material-tissue/ skin compatibility.</td>
</tr>
</table>

Biocompatibility	Cytotoxicity Acute Systemic Toxicity Intracutaneous Reactivity Hemocompatibility Bacterial Endotoxin Justification - Subacute/Subchronic Toxicity Sensitization	Cytotoxicity Sensitization Irritation or Intracutaneous Reactivity Systemic Toxicity (Acute) Hemocompatibility	The subject device biocompatibility testing encompasses predicate device endpoint testing.
Sterilization	EO Sterility Assurance Level (SAL) of 10-6	Same	
Shelf-Life	3 years	Same	
Environment of Use	Professional Healthcare Facility Home Environment Magnetic Resonance (MR) Environment Transport (Ambulatory) Environment	Same	
Clinical Studies	Not Required	Same	

1.Weight and Dimensions: Any size and weight differences between the subject and predicate device are negligible, and do not raise new or different questions of device safety and effectiveness.

2.Flow Accuracy and Rate: The subject device flow rates and flow accuracies of the subject device is encompassed within the predicate device. Flow rate and accuracy was confirmed with performance testing, and do not raise new or different questions of device safety and effectiveness.

3.Material: The material composition of the predicate device is not provided, however, it is not needed as the appropriate biocompatibility endpoint testing was provided for subject device material-tissue/ skin compatibility. There are no new or different questions of device safety and effectiveness.

Performance Data

InfuLife was tested to the following standards:

- AAMI TIR101:2021 – Fluid Delivery Performance Testing for Infusion Pumps

- ISO 28620:2020 – Medical Devices – Non-Electrically Driven Portable Infusion Devices
- AAMI TIR38:2019 – Medical Device Safety and Assurance Guidance
- ANSI AAMI ISO 14971:2019 – Medical Devices – Application of Risk Management to Medical Devices
- ANSI AAMI ISO 10993-1:2018 – Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process
- ANSI AAMI ISO 10993-10:2019/R2014 – Biological Evaluation of Medica Devices – Part 10: Tests for Irritation and Skin Sensitization
- ANSI AAMI ISO 10993-11:2017 – Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity
- ANSI AAMI ISO 10993-4:2017 – Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood
- ANSI AAMI ISO 10993-5:2009/R2014 – Biological Evaluation of Medical Devices – Part 5: Tests for in vitro Cytotoxicity
- ANSI AAMI ISO 1135:2014A1:2018 – Sterilization of Health-Care Products – Ethylene Oxide – Requirements for the Development Validation and Routine Control of a Sterilization Process for Medical Devices
- ISO 10993-7 Second Editions 2008 – Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals
- ANSI AAMI ISO 11607-1:2019 – Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials Sterile Barrier Systems and Packaging Systems
- ASTM F1980-16 – Standard Guide for Accelerated Aging of Sterile barrier Systems for Medical Devices
- ASTM F209611:2019 – Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM F1886/F1886M-16 – Standard Test Method for Determining Integrity of Seals for flexible Packaging by Visual Inspection
- ANSI AAMI ISO 11607-2:2019 – Packaging for Terminally Sterilized Medical Devices – part 2: Validation Requirements for Forming, Sealing, and Assembly process
- USP-NF <85> - Bacterial Endotoxins Test

All tests met acceptance criteria.

Animal and Clinical Studies

No animal study or clinical trial data was obtained in support of this submission.

Conclusion

The data, test results, and analysis provide evidence that InfuLife is substantially equivalent to the predicate device, and that the device raises no new or different questions of safety and effectiveness.