



July 28, 2025

Baxter Healthcare Corporation
Jessica Andreshak
Senior Manager, Regulatory Affairs
One Baxter Parkway
Deerfield, Illinois 60015

Re: K251640

Trade/Device Name: SIGMA Spectrum Infusion Pump with Master Drug Library
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN, PHC
Dated: May 29, 2025
Received: May 29, 2025

Dear Jessica Andreshak:

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, Infusion Devices

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

Indications for Use

510(k) Number (if known)

K251640

Device Name

SIGMA Spectrum Infusion Pump with Master Drug Library

Indications for Use (Describe)

The SIGMA Spectrum Infusion Pump with Master Drug Library is intended to be used for the controlled administration of fluids. These may include pharmaceutical drugs, blood, blood products and mixtures of required patient therapy. The intended routes of administration consist of the following clinically accepted routes: intravenous, arterial, subcutaneous, or epidural. The SIGMA Spectrum Infusion Pump with Master Drug Library is intended to be used in conjunction with legally marketed and compatible intravenous administration sets and medications provided by the user.

The SIGMA Spectrum Infusion Pump with Master Drug Library is suitable for a variety of patient care environments such as, but not limited to, hospitals and outpatient care areas.

The SIGMA Spectrum Infusion Pump with Master Drug Library is intended to reduce operator interaction through guided programming, thereby helping to reduce errors. The SIGMA Spectrum Infusion Pump with Master Drug Library is intended to be used by trained 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.

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510(k) Summary

Date: July 14, 2025

Owner: Baxter Healthcare Corporation
711 Park Avenue
Medina, New York 14103
Registration No: 1314492

Contact: Jessica Andreshak
Sr. Manager, Regulatory Affairs
25212 W. Illinois Route 120
Round Lake, IL 60073
Telephone: (262) 716-3028
Jessica_Andreshak@Baxter.com

Trade / Device Name: SIGMA Spectrum Infusion Pump with Master Drug Library

Classification Panel: 80 General Hospital

Regulation Name: Pump, Infusion

Regulation Number: 21 CFR 880.5725

Regulatory Class: Class II

Product Code: FRN

Assoc. Product Code: PHC

Predicate Device: The subject device is substantially equivalent to the following predicate device:

- SIGMA Spectrum Infusion Pump with Master Drug Library; cleared March 31, 2023 (K230022).

Device Description: SIGMA Spectrum is a large volume pump within the SIGMA Spectrum infusion system used by clinicians at the patient bedside to control the delivery of medications from a bag. The pump moves fluid from the bag to the patient via specified administration sets using a peristaltic pumping action. The pump offers various programmable delivery

modes to address specific patient care needs. The delivery modes available to support the patient are determined by how the pump and its associated drug library are configured.

The pump provides delivery of fluids into a patient in a controlled manner, as identified in 21 CFR 880.5725. The system includes a software controlled, electromechanical pump used for the controlled administration of fluids including pharmaceutical drugs, blood, blood products, and mixtures of required patient therapy through administration sets at clinician's selectable rates and volumes.

The pump is intended for the controlled administration of fluids through the following clinically accepted routes of administration: intravenous, arterial, subcutaneous, and epidural. The pump is intended to be used in conjunction with legally marketed and compatible administration sets, as indicated in the device labeling, and medications provided by the user. The subject device is suitable for patient care in hospitals and outpatient health care facilities.

The Master Drug Library (MDL) is a stand-alone (not embedded in the pump) software application installed on a hospital-provided computing platform and used to create a drug library file. MDL facilitates the generation, configuration, and management of a facility-specific drug library file for dedicated infusion pumps. The drug library file includes customers' dosing limits and additional pump configuration settings. The drug library file is intended to be distributed to all compatible infusion pumps in the hospital.

This submission includes software design and labeling changes to address the issues leading to recalls Z-0530-2022 and Z-2103-2023.

**Intended Use /
Indications for Use:**

The SIGMA Spectrum Infusion Pump with Master Drug Library is intended to be used for the controlled administration of fluids. These may include pharmaceutical

drugs, blood, blood products and mixtures of required patient therapy. The intended routes of administration consist of the following clinically accepted routes: intravenous, arterial, subcutaneous, or epidural. The SIGMA Spectrum Infusion Pump with Master Drug Library is intended to be used in conjunction with legally marketed and compatible intravenous administration sets and medications provided by the user.

The SIGMA Spectrum Infusion Pump with Master Drug Library is suitable for a variety of patient care environments such as, but not limited to, hospitals and outpatient care areas.

The SIGMA Spectrum Infusion Pump with Master Drug Library is intended to reduce operator interaction through guided programming, thereby helping to reduce errors. The SIGMA Spectrum Infusion Pump with Master Drug Library is intended to be used by trained healthcare professionals.

**Technological
Characteristics:**

The subject device is substantially equivalent to the primary predicate device (K230022) with regards to design, performance and intended use. The following table provides a comparison summary of the technical characteristics of each device.

Characteristic	Subject Device	Predicate Device (K230022)
SIGMA Spectrum Infusion Pump		
Pumping Mechanism	Linear peristaltic design	Linear peristaltic design
Modes of Delivery	Continuous, Intermittent	Continuous, Intermittent
Routes of Administration	- Intravenous - Arterial - Subcutaneous - Epidural	- Intravenous - Arterial - Subcutaneous - Epidural
User Interface Display	Color LCD	Color LCD
AC Power	Input (P/N 35727): 115 VAC $\pm$15%, 50 - 60 Hz / 300 mA Max	Input (P/N 35727): 115 VAC $\pm$15%, 50 - 60 Hz / 300 mA Max

Characteristic	Subject Device	Predicate Device (K230022)
	Output (P/N 35727): 9 VDC/1200 mA, short circuit protected	Output (P/N 35727): 9 VDC/1200 mA, short circuit protected
Operational Conditions	- With Standard Battery or 802.11a/b/g/n WBM: Operating temperature: 15.6 to 32.2°C (60 to 90°F), 20 to 90% relative humidity non-condensing - With 802.11b/g WBM: Operating temperature: 15.6 to 26.7°C (60 to 80°F), 20 to 90% relative humidity non-condensing	- With Standard Battery or 802.11a/b/g/n WBM: Operating temperature: 15.6 to 32.2°C (60 to 90°F), 20 to 90% relative humidity non-condensing - With 802.11b/g WBM: Operating temperature: 15.6 to 26.7°C (60 to 80°F), 20 to 90% relative humidity non-condensing
Storage and Packing Conditions	- With Standard Battery: Storage temperature: -10 to +49°C (14 to 120°F), 10 to 90% relative humidity non-condensing - With Wireless Battery Module: Storage temperature: -10 to +49°C (14 to 120°F), 10 to 90% relative humidity non-condensing	- With Standard Battery: Storage temperature: -10 to +49°C (14 to 120°F), 10 to 90% relative humidity non-condensing - With Wireless Battery Module: Storage temperature: -10 to +49°C (14 to 120°F), 10 to 90% relative humidity non-condensing
Overall Size (Pump)	With Standard Battery - Without IV pole clamp: Height 14.7 cm (5.8 in); Width 10.6 cm (4.2 in); Depth 6.35 cm (2.5 in) - With IV pole clamp: Height 14.7 cm (5.8 in); Width 16.76 cm (6.6 in); Depth 11.93 cm (4.7 in) With 802.11b/g WBM - Without IV pole clamp: Height 16 cm (6.3 in); Width 10.6 cm (4.2 in); Depth 6.35 cm (2.5 in) - With IV pole clamp: Height 16 cm (6.3 in); Width 16.76 cm (6.6 in); Depth 11.93 cm (4.7 in) With 802.11a/b/g/n WBM - Without IV pole clamp: Height 16.76 cm (6.6 in); Width 10.6 cm (4.2 in); Depth 6.35 cm (2.5 in) - With IV pole clamp: Height 16.76 cm (6.6 in); Width 16.76 cm (6.6 in); Depth 11.93 cm (4.7 in)	With Standard Battery - Without IV pole clamp: Height 14.7 cm (5.8 in); Width 10.6 cm (4.2 in); Depth 6.35 cm (2.5 in) - With IV pole clamp: Height 14.7 cm (5.8 in); Width 16.76 cm (6.6 in); Depth 11.93 cm (4.7 in) With 802.11b/g WBM - Without IV pole clamp: Height 16 cm (6.3 in); Width 10.6 cm (4.2 in); Depth 6.35 cm (2.5 in) - With IV pole clamp: Height 16 cm (6.3 in); Width 16.76 cm (6.6 in); Depth 11.93 cm (4.7 in) With 802.11a/b/g/n WBM - Without IV pole clamp: Height 16.76 cm (6.6 in); Width 10.6 cm (4.2 in); Depth 6.35 cm (2.5 in) - With IV pole clamp: Height 16.76 cm (6.6 in); Width 16.76 cm (6.6 in); Depth 11.93 cm (4.7 in)
Weight (Pump)	Pump with Standard Battery Module - Without IV pole clamp: 25.5oz ± 1.0 oz - With IV pole clamp: 33.5 oz ±1.0 oz	Pump with Standard Battery Module - Without IV pole clamp: 25.5oz ± 1.0 oz - With IV pole clamp: 33.5 oz ±1.0 oz

Characteristic	Subject Device	Predicate Device (K230022)
	Pump with Wireless Battery Module - Without IV pole clamp: 26.5oz $\pm$ 1.0 oz - With IV pole clamp: 34.5oz $\pm$ 1.0 oz	Pump with Wireless Battery Module - Without IV pole clamp: 26.5oz $\pm$ 1.0 oz - With IV pole clamp: 34.5oz $\pm$ 1.0 oz
Timekeeping	Real Time Clock, battery backed, 10-year life	Real Time Clock, battery backed, 10-year life
Logging Memory	Yes	Yes
Single Fault Condition	A maximum bolus of 0.56 mL may be generated as a result of a Single Fault Condition (a failure of the SIGMA Spectrum Infusion Pump, which stops the pump motor and results in an alarm)	A maximum bolus of 0.56 mL may be generated as a result of a Single Fault Condition (a failure of the SIGMA Spectrum Infusion Pump, which stops the pump motor and results in an alarm)
Anti-Free Flow System	Set-based, utilizing IV set slide clamp	Set-based, utilizing IV set slide clamp
Auto-programming	No	No
Battery Power and Capacity	Standard Battery - Lithium Ion, 7.4 VDC nominal. - Capacity at intermediate rate 8 hrs (at 25 mL/hr at the highest backlight settings) - Capacity 8 hrs (at 125 mL/hr at the highest backlight settings) 12 hr. recharge time at 72°F $\pm$ 2°F - Charging occurs if AC Power Adaptor is plugged in, whether the Pump is on or off 802.11b/g WBM - Lithium Ion, 7.4 VDC nominal. - Capacity at intermediate rate 5 hrs (at 25 mL/hr at the highest backlight settings) - Capacity 4 hrs (at 125 mL/hr at the highest backlight settings) 16 hr. recharge time at 72°F $\pm$ 2°F - Charging occurs if AC Power Adaptor is plugged in, whether the Pump is on or off 802.11a/b/g/n WBM - Lithium Ion, 7.4 VDC nominal. - Capacity at intermediate rate 5 hrs (at 25 mL/hr at the highest backlight settings) - Capacity 4 hrs (at 125 mL/hr at the highest backlight settings)	Standard Battery - Lithium Ion, 7.4 VDC nominal. - Capacity at intermediate rate 8 hrs (at 25 mL/hr at the highest backlight settings) - Capacity 8 hrs (at 125 mL/hr at the highest backlight settings) 12 hr. recharge time at 72°F $\pm$ 2°F - Charging occurs if AC Power Adaptor is plugged in, whether the Pump is on or off 802.11b/g WBM - Lithium Ion, 7.4 VDC nominal. - Capacity at intermediate rate 5 hrs (at 25 mL/hr at the highest backlight settings) - Capacity 4 hrs (at 125 mL/hr at the highest backlight settings) 16 hr. recharge time at 72°F $\pm$ 2°F - Charging occurs if AC Power Adaptor is plugged in, whether the Pump is on or off 802.11a/b/g/n WBM - Lithium Ion, 7.4 VDC nominal. - Capacity at intermediate rate 5 hrs (at 25 mL/hr at the highest backlight settings) - Capacity 4 hrs (at 125 mL/hr at the highest backlight settings)

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Alarm Volume	Variable (three levels: high, medium and low)	Variable (three levels: high, medium and low)																																										
Low Battery Alarm	Very Low Battery: ≤15 minutes of battery power remaining	Very Low Battery: ≤15 minutes of battery power remaining																																										
Due for Inspection Alarm	Due for inspection: Preventive Maintenance and/or Network Certification.	Due for inspection: Preventive Maintenance and/or Network Certification.																																										
Air-In-Line Alarm	Dual-beam ultrasonic detector alarms for large bubbles but allows smaller bubbles to pass. - Detects air bubbles >2.5 cm (>1 in) (approximately 140 µL in Baxter sets) - Detects >1 mL of accumulated air over 15 min., excluding <10 µL bubbles, at room temperature - Detects >1.5 mL of accumulated air over 15 min., excluding <10 µL bubbles, at 15.5°C (60°F)	Dual-beam ultrasonic detector alarms for large bubbles but allows smaller bubbles to pass. - Detects air bubbles >2.5 cm (>1 in) (approximately 140 µL in Baxter sets) - Detects >1 mL of accumulated air over 15 min., excluding <10 µL bubbles, at room temperature - Detects >1.5 mL of accumulated air over 15 min., excluding <10 µL bubbles, at 15.5°C (60°F)																																										
Downstream Occlusion Alarms	When the Downstream Occlusion Automatic Restart is enabled, automatic restart occurs after the downstream occlusion is cleared. Actuation can be set to: - Low, 41 kPa ±27 kPa (6 ±4 psi) - Medium, 89 kPa ±41 kPa (13 ±6 psi) - High, 131 kPa ±62 kPa (19 ±9 psi)	When the Downstream Occlusion Automatic Restart is enabled, automatic restart occurs after the downstream occlusion is cleared. Actuation can be set to: - Low, 41 kPa ±27 kPa (6 ±4 psi) - Medium, 89 kPa ±41 kPa (13 ±6 psi) - High, 131 kPa ±62 kPa (19 ±9 psi)																																										
Upstream Occlusion Time to Alarm	Time to detect USO is dependent on occlusion distance and flow rate. Time to detection for an USO 50.8 cm (20 in.) from the top of the pump at nominal temperature of 22.2°C±1.1°C (72°F±2°F) is as follows: <table border="1"> <thead> <tr> <th>Flow Rate</th><th>Initial Time to Alarm, 95% Confidence/ 99% Population</th><th>Initial Time to Alarm, Median Value</th></tr> </thead> <tbody> <tr> <td>0.5 mL/hr</td><td><14 hours</td><td>42 minutes, 47 seconds</td></tr> <tr> <td>1 mL/hr</td><td><7 hours</td><td>20 minutes, 4 seconds</td></tr> <tr> <td>5 mL/hr</td><td><1 hour</td><td>4 minutes, 7 seconds</td></tr> <tr> <td>25 mL/hr</td><td><50 minutes</td><td>49 seconds</td></tr> <tr> <td>100 mL/hr</td><td><8 minutes</td><td>14 seconds</td></tr> <tr> <td>999 mL/hr</td><td><2 minutes</td><td>4.5 seconds</td></tr> </tbody> </table>	Flow Rate	Initial Time to Alarm, 95% Confidence/ 99% Population	Initial Time to Alarm, Median Value	0.5 mL/hr	<14 hours	42 minutes, 47 seconds	1 mL/hr	<7 hours	20 minutes, 4 seconds	5 mL/hr	<1 hour	4 minutes, 7 seconds	25 mL/hr	<50 minutes	49 seconds	100 mL/hr	<8 minutes	14 seconds	999 mL/hr	<2 minutes	4.5 seconds	Time to detect USO is dependent on occlusion distance and flow rate. Time to detection for an USO 50.8 cm (20 in.) from the top of the pump at nominal temperature of 22.2°C±1.1°C (72°F±2°F) is as follows: <table border="1"> <thead> <tr> <th>Flow Rate</th><th>Initial Time to Alarm, 95% Confidence/ 99% Population</th><th>Time to Alarm, Median Value</th></tr> </thead> <tbody> <tr> <td>0.5 mL/hr</td><td><14 hours</td><td>1 hour, 47 minutes</td></tr> <tr> <td>1 mL/hr</td><td><7 hours</td><td>48 minutes, 53 seconds</td></tr> <tr> <td>5 mL/hr</td><td><1 hour</td><td>9 minutes, 56 seconds</td></tr> <tr> <td>25 mL/hr</td><td><50 minutes</td><td>5 minutes, 48 seconds</td></tr> <tr> <td>100 mL/hr</td><td><8 minutes</td><td>1 minute, 6 seconds</td></tr> <tr> <td>999 mL/hr</td><td><2 minutes</td><td>20 seconds</td></tr> </tbody> </table>	Flow Rate	Initial Time to Alarm, 95% Confidence/ 99% Population	Time to Alarm, Median Value	0.5 mL/hr	<14 hours	1 hour, 47 minutes	1 mL/hr	<7 hours	48 minutes, 53 seconds	5 mL/hr	<1 hour	9 minutes, 56 seconds	25 mL/hr	<50 minutes	5 minutes, 48 seconds	100 mL/hr	<8 minutes	1 minute, 6 seconds	999 mL/hr	<2 minutes	20 seconds
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Infusion Modes	- Continuous (Primary and Secondary) - Multi-Step	- Continuous (Primary and Secondary) - Multi-Step																																										

Characteristic	Subject Device	Predicate Device (K230022)																																				
	- Cyclic TPN - Amount/Time (Primary/Secondary)	- Cyclic TPN - Amount/Time (Primary/Secondary)																																				
Dose Modes - Continuous Infusion	mL/hr, mL/kg/min, mL/kg/hr, g/hr, mg/hr, mg/kg/hr, mg/min, mg/kg/min, mg/kg/day, mcg/hr, mcg/kg/hr, mcg/min, mcg/kg/min, mcg/kg/day, ng/min, ng/kg/min, Units/hr, Units/kg/hr, Units/min, Units/kg/min, mUnits/min, mUnits/kg/hr, mUnits/kg/min, mEq/hr, mEq/kg/hr, mmol/hr, mmol/kg/hr	mL/hr, mL/kg/min, mL/kg/hr, g/hr, mg/hr, mg/kg/hr, mg/min, mg/kg/min, mg/kg/day, mcg/hr, mcg/kg/hr, mcg/min, mcg/kg/min, mcg/kg/day, ng/min, ng/kg/min, Units/hr, Units/kg/hr, Units/min, Units/kg/min, mUnits/min, mUnits/kg/hr, mUnits/kg/min, mEq/hr, mEq/kg/hr, mmol/hr, mmol/kg/hr																																				
Dose Modes – Loading Dose and Bolus	mL, mL/kg, g, g/kg, mg, mg/kg, mcg, mcg/kg, ng, ng/kg, Units, Units/kg, mUnits, mUnits/kg, mEq, mEq/kg, mmol, mmol/kg	mL, mL/kg, g, g/kg, mg, mg/kg, mcg, mcg/kg, ng, ng/kg, Units, Units/kg, mUnits, mUnits/kg, mEq, mEq/kg, mmol, mmol/kg																																				
Dose Modes – Amount/Time Infusions	mL, mL/kg, g, g/kg, g/m², mg, mg/kg, mg/m², mcg, mcg/kg, mcg/m², Units, Units/kg, Units/m², mEq, mEq/kg, mmol, mmol/kg	mL, mL/kg, g, g/kg, g/m², mg, mg/kg, mg/m², mcg, mcg/kg, mcg/m², Units, Units/kg, Units/m², mEq, mEq/kg, mmol, mmol/kg																																				
Flow Rate	0.5 to 999 mL/hr with 0.1 mL/hr increments from 0.5 to 99.9 mL/hr and 1.0 mL/hr increments from 100 to 999 mL/hr	0.5 to 999 mL/hr with 0.1 mL/hr increments from 0.5 to 99.9 mL/hr and 1.0 mL/hr increments from 100 to 999 mL/hr																																				
Low-Flow Continuity	The maximum period of no-flow is 90 seconds at a flow rate of 0.5 mL/hr.	The maximum period of no-flow is 90 seconds at a flow rate of 0.5 mL/hr.																																				
Keep Vein Open (KVO) Rate	Yes	Yes																																				
Downstream Occlusion Pressure	User adjustable downstream occlusion pressure settings: - Low, 41 kPa ±27 kPa (6 ±4 psi) - Medium, 89 kPa ±41 kPa (13 ±6 psi) - High, 131 kPa ±62 kPa (19 ±9 psi) Maximum allowable pressure while in downstream occlusion: 207 kPa (30 psi)	User adjustable downstream occlusion pressure settings: - Low, 41 kPa ±27 kPa (6 ±4 psi) - Medium, 89 kPa ±41 kPa (13 ±6 psi) - High, 131 kPa ±62 kPa (19 ±9 psi) Maximum allowable pressure while in downstream occlusion: 207 kPa (30 psi)																																				
Bolus Capability	Yes	Yes																																				
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Characteristic	Subject Device	Predicate Device (K230022)																																				
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Rate or Dose Limits	0.5 – 999 mL/hr	0.5 – 999 mL/hr																																				
Wireless Capability	Yes	Yes																																				
Wireless Security	WPA/WPA2/802.11i - Encryption: TKIP, CCMP (AES), Mixed-Mode (AES+TKIP) - Wireless Security: WPA-PSK, WPA2-PSK 802.1X authentication: PEAP/MSCHAPv2; EAP-FAST; EAP-TLS; EAP-TTLS/PAP; EAP-TTLS/MSCHAPv2	WPA/WPA2/802.11i - Encryption: TKIP, CCMP (AES), Mixed-Mode (AES+TKIP) - Wireless Security: WPA-PSK, WPA2-PSK 802.1X authentication: PEAP/MSCHAPv2; EAP-FAST; EAP-TLS; EAP-TTLS/PAP; EAP-TTLS/MSCHAPv2																																				
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Drug Library Capacity	- Number of Care Areas: 32 - Number of Drugs: 5000 - Number of Clinical Advisories: 400 - Number of Modifiers: 500	- Number of Care Areas: 32 - Number of Drugs: 5000 - Number of Clinical Advisories: 400 - Number of Modifiers: 500																																				
Available Limits	Upper Hard Limit must be greater than or equal to Upper Soft Limit.	Upper Hard Limit must be greater than or equal to Upper Soft Limit.																																				

Characteristic	Subject Device	Predicate Device (K230022)
	- Upper Soft Limit must be greater than or equal to a Starting Rate. - Starting Rate must be greater than or equal to a Lower Soft Limit. - Lower Soft Limit must be greater than or equal to a Lower Hard Limit. - Lower Hard Limit must be less than or equal to a Lower Soft Limit - All Rates and Drug Library Limits must fall within Spectrum Pump operational range of 0.5 to 999 mL/hr.	- Upper Soft Limit must be greater than or equal to a Starting Rate. - Starting Rate must be greater than or equal to a Lower Soft Limit. - Lower Soft Limit must be greater than or equal to a Lower Hard Limit. - Lower Hard Limit must be less than or equal to a Lower Soft Limit - All Rates and Drug Library Limits must fall within Spectrum Pump operational range of 0.5 to 999 mL/hr.
Security Roles	- Read-Only Access - Limited Access - Full Access	- Read-Only Access - Limited Access - Full Access
Reports	- Standard and custom Drug and Fluid Report for Drugs/Fluids, Concentration Limits, Configurations, etc. - Audit reports for a list of changes made to the Drug Library along with the date the change was performed	- Standard and custom Drug and Fluid Report for Drugs/Fluids, Concentration Limits, Configurations, etc. - Audit reports for a list of changes made to the Drug Library along with the date the change was performed
Gateway	CareEverywhere Gateway Version 16 and higher.	CareEverywhere Gateway Version 16 and higher.

Summary of Testing: Non-clinical testing has been executed against requirements for performance and safety, and to provide objective evidence that the subject device's intended use is met. Testing compared the subject device to a previous version of the subject device (K133081). Non-clinical testing met all acceptance criteria, demonstrating that the device is safe and effective for its intended use.

Conclusion: The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The SIGMA Spectrum Infusion Pump with Master Drug Library is substantially equivalent to the SIGMA Spectrum Infusion Pump with Master Drug Library cleared under K230022 with respect to the indications for use, target

populations, treatment method, and technological characteristics.