July 28, 2025

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

Re: K251636
Trade/Device Name: Spectrum IQ Infusion System with Dose IQ Safety Software (3570009)
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

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)*
K251636

Device Name
Spectrum IQ Infusion System with Dose IQ Safety Software

Indications for Use *(Describe)*
The Spectrum IQ Infusion System with Dose IQ Safety Software is intended to be used for the controlled administration of fluids. These may include pharmaceutical drugs, blood, and blood products. The intended routes of administration consist of the following clinically accepted routes: intravenous, arterial, subcutaneous, or epidural. The Spectrum IQ Infusion System with Dose IQ Safety Software is intended to be used in conjunction with legally marketed and compatible intravenous administration sets and medications provided by the user.

The Spectrum IQ Infusion System with Dose IQ Safety Software is suitable for a variety of patient care environments such as, but not limited to, hospitals and outpatient care areas.

The Spectrum IQ Infusion System with Dose IQ Safety Software is intended to reduce operator interaction through guided programming, including a way to automate the programming of infusion parameters and documentation of infusion therapies. This automation is intended to reduce pump programming errors.

The Spectrum IQ Infusion System with Dose IQ Safety Software 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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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."

Baxter

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:	Spectrum IQ Infusion System with Dose IQ Safety Software
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: • Spectrum IQ Infusion System with Dose IQ Safety Software; cleared March 31, 2023 (K230041).
Device Description:	Spectrum IQ is a large volume pump within the Spectrum IQ 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 and blood products 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.

Dose IQ is a standalone software application installed on a hospital-provided computing platform and used to create a drug library file. Dose IQ 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-0529-2022 and Z-2104-2023.

Intended Use / Indications for Use:

The Spectrum IQ Infusion System with Dose IQ Safety Software is intended to be used for the controlled administration of fluids. These may include pharmaceutical drugs, blood, and blood products. The intended routes of administration consist of the following clinically accepted

routes: intravenous, arterial, subcutaneous, or epidural. The Spectrum IQ Infusion System with Dose IQ Safety Software is intended to be used in conjunction with legally marketed and compatible intravenous administration sets and medications provided by the user.

The Spectrum IQ Infusion System with Dose IQ Safety Software is suitable for a variety of patient care environments such as, but not limited to, hospitals and outpatient care areas.

The Spectrum IQ Infusion System with Dose IQ Safety Software is intended to reduce operator interaction through guided programming, including a way to automate the programming of infusion parameters and documentation of infusion therapies. This automation is intended to reduce pump programming errors.

The Spectrum IQ Infusion System with Dose IQ Safety Software is intended to be used by trained healthcare professionals.

Technological Characteristics:

The subject device is substantially equivalent to the primary predicate device (K230041) 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 (K230041)
Spectrum IQ Infusion System		
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

Characteristic	Subject Device	Predicate Device (K230041)
User Interface Display	Color LCD	Color LCD
AC Power	• Input: 100-240 VAC, 50 / 60 Hz / 300 mA Max • Output: 9 VDC/1000 mA, short circuit protected	• Input: 100-240 VAC, 50 / 60 Hz / 300 mA Max • Output: 9 VDC/1000 mA, short circuit protected
Operational Conditions	With 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. • Atmospheric Pressure: 66kPa to 102kPa	With 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. • Atmospheric Pressure: 66kPa to 102kPa
Storage and Packing Conditions	With Wireless Battery Module • Storage temperature: -10 to +35°C (14 to 95°F), 10 to 90% relative humidity non-condensing	With Wireless Battery Module • Storage temperature: -10 to +35°C (14 to 95°F), 10 to 90% relative humidity non-condensing
Overall Size (Pump)	With Wireless Battery Module: • Without IV pole clamp - 8.0”h x 5.7”w x 3.6”d • With standard IV pole clamp - 8.0”h x 8.2”w x 5.9”d	With Wireless Battery Module: • Without IV pole clamp - 8.0”h x 5.7”w x 3.6”d • With standard IV pole clamp - 8.0”h x 8.2”w x 5.9”d
Weight (Pump)	Pump alone (no WBM or pole clamp) = 861.97g Pump with Wireless Battery Module • Without IV pole clamp: 1.235 kg (45.6 oz ± 1.0 oz) • With IV pole clamp: 1.462 kg (51.6 oz ±1.0 oz)	Pump alone (no WBM or pole clamp) = 861.97g Pump with Wireless Battery Module • Without IV pole clamp: 1.235 kg (45.6 oz ± 1.0 oz) • With IV pole clamp: 1.462 kg (51.6 oz ±1.0 oz)
Timekeeping	Real Time Clock, battery backed, 7-year life	Real Time Clock, battery backed, 7-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 Spectrum IQ Infusion System, 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 Spectrum IQ Infusion System, 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	Yes	Yes
Battery Weight	Wireless Battery Module = 155.19g	Wireless Battery Module = 155.19g

Characteristic	Subject Device	Predicate Device (K230041)
Battery Power	802.11 a/b/g/n Wireless Battery Module • Lithium Ion, minimum 1700 mA/h, 7.4 VDC nominal • 16 hour recharge time • Charging occurs if AC Power Adaptor is plugged in, whether pump is ON or OFF	802.11 a/b/g/n Wireless Battery Module • Lithium Ion, minimum 1700 mA/h, 7.4 VDC nominal • 16 hour recharge time • Charging occurs if AC Power Adaptor is plugged in, whether pump is ON or OFF
Battery Capacity	• Capacity at intermediate rate 5 hrs (at 25 mL/hr at the highest backlight settings) • Capacity 4 hours (at 125 mL/hr at the highest backlight settings) • Capacity 3.1 hrs (at 999 mL/hr at highest backlight setting on and Wi-Fi on)	• Capacity at intermediate rate 5 hrs (at 25 mL/hr at the highest backlight settings) • Capacity 4 hours (at 125 mL/hr at the highest backlight settings) • Capacity 3.1 hrs (at 999 mL/hr at highest backlight setting on and Wi-Fi on)
Alarms	Per IEC 60601-1-8	Per IEC 60601-1-8
Alarm Volume	Variable (three levels: high, medium and low)	Variable (three levels: high, medium and low)
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) NOTE: Air bubbles >= 50 µL are counted towards accumulated air. Air bubbles < 10 µL are excluded towards accumulated air. When detected, air bubbles < 50 µL and > 10 µL are counted as 50 µL towards accumulated air. This algorithm was tested using 35 µL air bubbles.	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) NOTE: Air bubbles >= 50 µL are counted towards accumulated air. Air bubbles < 10 µL are excluded towards accumulated air. When detected, air bubbles < 50 µL and > 10 µL are counted as 50 µL towards accumulated air. This algorithm was tested using 35 µL air bubbles.
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)	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)

<table>
<tr><th>Characteristic</th><th>Subject Device</th><th>Predicate Device (K230041)</th></tr>
<tr><td></td><td>• Medium, 89 kPa ±41 kPa (13 ±6 psi
• High, 131 kPa ±62 kPa (19 ±9 psi)</td><td>• Medium, 89 kPa ±41 kPa (13 ±6 psi
• High, 131 kPa ±62 kPa (19 ±9 psi)</td></tr>
<tr><td>Upstream Occlusion Time to Alarm</td><td>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>
<tr><th>Flow Rate</th><th>Initial Time to Alarm, 95% Confidence/ 99% Population</th><th>Initial Time to Alarm, Median Value</th></tr>
<tr><td>0.5 mL/hr</td><td><14 hours</td><td>46 minutes, 4 seconds</td></tr>
<tr><td>1 mL/hr</td><td><7 hours</td><td>33 minutes, 15 seconds</td></tr>
<tr><td>5 mL/hr</td><td><1 hour</td><td>5 minutes, 30 seconds</td></tr>
<tr><td>25 mL/hr</td><td><50 minutes</td><td>1 minutes, 20 seconds</td></tr>
<tr><td>100 mL/hr</td><td><8 minutes</td><td>55 seconds</td></tr>
<tr><td>999 mL/hr</td><td><2 minutes</td><td>7 seconds</td></tr>
</table></td><td>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>
<tr><th>Flow Rate</th><th>Initial Time to Alarm, 95% Confidence/ 99% Population</th><th>Time to Alarm, Median Value</th></tr>
<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>
</table></td></tr>
<tr><td>Low Battery Alarm</td><td>Very Low Battery: ≤15 minutes of battery power remaining</td><td>Very Low Battery: ≤15 minutes of battery power remaining</td></tr>
<tr><td>Due for Inspection Alarm</td><td>Due for inspection: Preventive Maintenance and/or Network Certification</td><td>Due for inspection: Preventive Maintenance and/or Network Certification</td></tr>
<tr><td>Infusion Modes</td><td>Continuous (Primary and Secondary), Multi-Step, Cyclic TPN, Amount/Time (Primary/Secondary) and Volume/Time</td><td>Continuous (Primary and Secondary), Multi-Step, Cyclic TPN, Amount/Time (Primary/Secondary) and Volume/Time</td></tr>
<tr><td>Dose Modes - Continuous Infusion</td><td>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</td><td>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</td></tr>
<tr><td>Dose Modes – Loading Dose and Bolus</td><td>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</td><td>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</td></tr>
<tr><td>Dose Modes – Amount/Time Infusions</td><td>mL, mL/kg, g, g/kg, g/m^2, mg, mg/kg, mg/m^2, mcg, mcg/kg, mcg/m^2, Units, Units/kg, Units/m^2, mEq, mEq/kg, mmol, mmol/kg</td><td>mL, mL/kg, g, g/kg, g/m^2, mg, mg/kg, mg/m^2, mcg, mcg/kg, mcg/m^2, Units, Units/kg, Units/m^2, mEq, mEq/kg, mmol, mmol/kg</td></tr>
<tr><td>Flow Rate</td><td>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</td><td>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</td></tr>
<tr><td>Low-Flow Continuity</td><td>• The maximum period of no-flow is 90 seconds at a flow rate of 0.5 mL/hr.</td><td>• The maximum period of no-flow is 90 seconds at a flow rate of 0.5 mL/hr.</td></tr>
</table>

<table>
<tr><th>Characteristic</th><th>Subject Device</th><th>Predicate Device (K230041)</th></tr>
<tr><td></td><td>• The maximum period of no-flow is 90 seconds with a bolus volume that does not exceed 15 µL over a 5 second sample volume interval at a flow rate of 0.5-1.0 mL/hr inclusive.</td><td>• The maximum period of no-flow is 90 seconds with a bolus volume that does not exceed 15 µL over a 5 second sample volume interval at a flow rate of 0.5-1.0 mL/hr inclusive.</td></tr>
<tr><td>Keep Vein Open (KVO) Rate</td><td>Yes</td><td>Yes</td></tr>
<tr><td>Occlusion Pressure</td><td>User adjustable downstream occlusion pressure settings:
• High (19 ±9 PSI)
• Medium (13 ±6 PSI)
• Low (6 ±4 PSI)
Maximum allowable pressure while in downstream occlusion:
• 207 kPa (30 psi)</td><td>User adjustable downstream occlusion pressure settings:
• High (19 ±9 PSI)
• Medium (13 ±6 PSI)
• Low (6 ±4 PSI)
Maximum allowable pressure while in downstream occlusion:
• 207 kPa (30 psi)</td></tr>
<tr><td>Bolus Capability</td><td>Yes</td><td>Yes</td></tr>
<tr><td>Bolus Volume Accuracy</td><td>Bolus Volume with DEHP Administration Sets
<table>
<tr><th>Set Type</th><th>Test</th><th>Bolus Delivery</th><th>Bolus Time</th><th>Bolus Rate</th><th>Delivery Accuracy</th></tr>
<tr><td>DEHP</td><td>Minimum Bolus Volume</td><td>0.5 mL</td><td>20 seconds</td><td>90 mL/hr</td><td>±20%</td></tr>
<tr><td>DEHP</td><td>Maximum Bolus Volume</td><td>999 mL</td><td>60 minutes</td><td>999 mL/hr</td><td>±10%</td></tr>
</table>
Bolus Volume with N-DEHP Administration Sets
<table>
<tr><th>Set Type</th><th>Test</th><th>Bolus Delivery</th><th>Bolus Time</th><th>Bolus Rate</th><th>Delivery Accuracy</th></tr>
<tr><td>N- DEHP</td><td>Minimum Bolus Volume</td><td>0.5 mL</td><td>20 seconds</td><td>90 mL/hr</td><td>±20%</td></tr>
<tr><td>N- DEHP</td><td>Maximum Bolus Volume</td><td>250mL</td><td>60 minutes</td><td>250 mL/hr</td><td>±10%</td></tr>
</table></td><td>Bolus Volume with DEHP Administration Sets
<table>
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<tr><td>DEHP</td><td>Maximum Bolus Volume</td><td>999 mL</td><td>60 minutes</td><td>999 mL/hr</td><td>±10%</td></tr>
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Bolus Volume with N-DEHP Administration Sets
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<tr><th>Set Type</th><th>Test</th><th>Bolus Delivery</th><th>Bolus Time</th><th>Bolus Rate</th><th>Delivery Accuracy</th></tr>
<tr><td>N- DEHP</td><td>Minimum Bolus Volume</td><td>0.5 mL</td><td>20 seconds</td><td>90 mL/hr</td><td>±20%</td></tr>
<tr><td>N- DEHP</td><td>Maximum Bolus Volume</td><td>250mL</td><td>60 minutes</td><td>250 mL/hr</td><td>±10%</td></tr>
</table></td></tr>
<tr><td>Volumetric Accuracy (DEHP)</td><td>Accuracy is based on volume collected over one hour using compatible Baxter (DEHP) Standard IV Sets.
<table>
<tr><th>Rate</th><th>Accuracy</th></tr>
<tr><td>0.5 – 1.9 mL/hr</td><td>±0.1 mL/hr</td></tr>
<tr><td>2.0 – 999 mL/hr</td><td>±5%</td></tr>
</table>
Specified accuracy is maintained on Baxter Standard IV Sets for up to 96 hours (maximum 12 liters) when tested at 72 +/-2 F.</td><td>Accuracy is based on volume collected over one hour using compatible Baxter (DEHP) Standard IV Sets.
<table>
<tr><th>Rate</th><th>Accuracy</th></tr>
<tr><td>0.5 – 1.9 mL/hr</td><td>±0.1 mL/hr</td></tr>
<tr><td>2.0 – 999 mL/hr</td><td>±5%</td></tr>
</table>
Specified accuracy is maintained on Baxter Standard IV Sets for up to 96 hours (maximum 12 liters) when tested at 72 +/-2 F.</td></tr>
<tr><td>Volumetric Accuracy (Non-DEHP)</td><td>Accuracy is based on volume collected over one hour using compatible Baxter non-DEHP Standard IV Sets.</td><td>Accuracy is based on volume collected over one hour using compatible Baxter non-DEHP Standard IV Sets.</td></tr>
</table>

Characteristic	Subject Device	Predicate Device (K230041)
	<table><tr><th>Rate</th><th>Accuracy</th><th>Tubing use</th></tr><tr><td>10 -125 mL/ hr</td><td>±10%</td><td>≤ 36 hrs</td></tr><tr><td>126- 250 mL/ hr</td><td>±10%</td><td>≤ 4 hrs</td></tr></table>	<table><tr><th>Rate</th><th>Accuracy</th><th>Tubing use</th></tr><tr><td>10 -125 mL/ hr</td><td>±10%</td><td>≤ 36 hrs</td></tr><tr><td>126- 250 mL/ hr</td><td>±10%</td><td>≤ 4 hrs</td></tr></table>
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
Dose IQ Safety Software		
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 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 Hard Limit must be greater than or equal to Upper Soft Limit. • 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

Characteristic	Subject Device	Predicate Device (K230041)
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. • IQ Enterprise Infusion Gateway V3.0.1 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 (K173084). 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 Spectrum IQ Infusion System with Dose IQ Safety Software is substantially equivalent to the Spectrum IQ Infusion System with Dose IQ Safety Software cleared under K230041 with respect to the indications for use, target populations, treatment method, and technological characteristics.