March 31, 2023

Baxter Healthcare Corporation
Meaghan Bonn
Principal Specialist, Regulatory Affairs
25212 W. Illinois Route 120
Round Lake, Illinois 60073

Re: K230041
Trade/Device Name: Baxter 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
Dated: December 21, 2022
Received: January 4, 2023

Dear Meaghan Bonn:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Office Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230041

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 and increase accuracy of infusion documentation.

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.

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

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"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."

Section 5. 510(k) Summary

FEBRUARY 6, 2023

OWNER:

Baxter Healthcare Corporation
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Deerfield, Illinois 60015

CONTACT PERSON:

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IDENTIFICATION OF THE DEVICE:

Common Name: Infusion Pump
Trade/Device Name: Spectrum IQ Infusion System with Dose IQ Safety Software
Classification Panel: 80 General Hospital
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN, PHC

Table 1. Product Codes for Spectrum IQ Infusion System with Dose IQ Safety Software

Code Number	Name
3570009	Spectrum IQ Infusion System
35723v091	Dose IQ Safety Software

PREDICATE DEVICE:

The Spectrum IQ Infusion System with Dose IQ Safety Software is substantially equivalent to the following predicate device: See Table 2 for predicate device.

Table 2. Predicate Device(s)

Device	Company	Predicate 510(k)	Clearance Date
Spectrum IQ Infusion System with Dose IQ Safety Software	Baxter Healthcare Corporation	K222048	2022-09-06

DESCRIPTION OF THE DEVICE:

The proposed device, Spectrum IQ Infusion System with Dose IQ Safety Software is a large volume infusion system that provides safe and effective 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 infusion of pharmaceutical drugs, blood and blood products through intravenous administration sets at user selectable rates and volumes, and a software application that allows the generation, configuration and management of a downloadable drug library into the pump.

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 and increase accuracy of infusion documentation.

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

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The intended use and function of the proposed device remains the same as the predicate device. The 510(k) premarket notification, K222048, of the predicate device was cleared on September 6, 2022.

DISCUSSION OF NONCLINICAL TESTS:

The scope of this notification is to update the algorithm and labeling related to the upstream occlusion alarm of the pump. Performance testing for the software was completed. Biocompatibility is not affected by this notification. The intended use and function of the proposed device is the same as the predicate device.

CONCLUSION:

The scope of this notification is to update the algorithm and labeling related to the upstream occlusion alarm of the pump per the performance testing. The intended use and function of the proposed device is equivalent to the predicate 510(k), currently commercialized device.