March 31, 2023

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

Re: K230022
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)*

Device Name
Baxter SIGMA Spectrum Infusion Pump with Master Drug Library

Indications for Use *(Describe)*
The Baxter 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, epidural or irrigation of fluid space. The Baxter 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 Baxter 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 Baxter SIGMA Spectrum Infusion Pump with Master Drug Library is intended to reduce operator interaction through guided programming, thereby helping to reduce errors. The Baxter 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.

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Section 5. 510(k) Summary

January 4, 2023

OWNER:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

CONTACT PERSON:

Meaghan Bonn
Principal Specialist, Global Regulatory Affairs
32650 N Wilson Road
Round Lake, IL 60073
Telephone: (224)270-6470
Fax: (224)270-4119

IDENTIFICATION OF THE DEVICE:

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

Code Number	Name
35700BAX2	SIGMA Spectrum Infusion System
35723v080	Master Drug Library

PREDICATE DEVICE:

The Baxter SIGMA Spectrum Infusion Pump with Master Drug Library 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
Baxter SIGMA Spectrum Infusion Pump with Master Drug Library	Baxter Healthcare Corporation	K133801	04/07/2014

DESCRIPTION OF THE DEVICE:

The Baxter SIGMA Spectrum Infusion Pump with Master Drug Library is a large volume infusion pump system that provides for safe and effective delivery of fluids into a patient in a controlled manner, as identified in 21 CFR, 880.5725. The pump is a software controlled, electromechanical device used for the infusion of pharmaceutical drugs, blood, blood products and mixtures of required patient therapy through administration sets at user selectable rates and volumes. The feedback-controlled, motorized pumping mechanism is of linear peristaltic design and uses inlet and outlet valves for flow control. The pump utilizes a primary and secondary processor to assure safe operation while providing infusion pump capabilities for a wide range of applications.

The pump is specifically manufactured and calibrated for the application of a manufacturer's brand of standard gravity administration sets, as indicated in the device labeling. For use, the administration set is loaded into the infusion pump. After acceptance of program parameters, the pump is started and fluid is propelled by the peristaltic action of the pumping mechanism against the outside surface of the administration set tubing. The pump is controlled to create smooth fluid dynamics, precision volumetric accuracy and uniformity of flow rate. None of the pump materials contact the administration set's fluid path.

The infusion pump is small in comparison to the traditional Large Volume Parenteral (LVP) infusion pumps currently on the market. It is designed to be used in a variety of patient care environments such as, but not limited to hospitals and outpatient care areas using an IV pole mounted configuration.

The Master Drug Library (MDL) Editor is a software application that allows the generation, configuration and management of a downloadable drug library into a SIGMA Spectrum infusion pump.

The drug library can be loaded directly into the SIGMA Spectrum infusion pump through a wireless network host or through an Infrared Data Association (IrDA) device. The MDL Editor software operates on a Microsoft Windows® platform.

Using the MDL Editor software application, a facility can provide preprogrammed delivery profiles, advisories and limits for a corresponding drug that is intended for a specific use classification or clinical care area, thus reducing the risk of medication errors.

The MDL Editor software application allows the ability to generate both standard or customized drug and fluid reports by clinical care area. The MDL Editor software application also provides a feature to restrict/limit the access of data to only appropriate personnel, providing additional security and rights to specific users.

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, and blood products. The intended routes of administration consist of the following clinically accepted routes: intravenous, arterial, subcutaneous, epidural or irrigation of fluid space. 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 Baxter 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 Baxter SIGMA Spectrum Infusion Pump with Master Drug Library is intended to reduce operator interaction through guided programming, thereby helping to reduce errors. The Baxter SIGMA Spectrum Infusion Pump with Master Drug Library 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, K133801, of the predicate device was cleared on May 7, 2014.

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.