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Contact:

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

Thomas Sampogna
Sr. Director, Regulatory Affairs
Phone: 224-270-4307
Fax: 847-786-5116
Email: thomas_sampogna@baxter.com

Trade Name: Baxter SIGMA Spectrum Infusion Pump with Master Drug Library
Model 35700

Common Name: Infusion Pump

Classification Name: Pump, Infusion

Classification: Infusion Pump as defined in 21 CFR 880.5725, Class II

Product Code: FRN, PHC

Predicate Device: The Baxter SIGMA Spectrum Infusion Pump with Master Drug Library is substantially equivalent to the following predicate device:

- SIGMA Spectrum and Spectrum with Master Drug Library, cleared Aug. 26, 2004 (K042121).

Device Description: 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.

Intended Use/ Indication for Use:

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.

Technological Characteristics:

The Baxter SIGMA Spectrum Infusion Pump with Master Drug Library is substantially equivalent to the predicate device with regards to design, performance and intended use. The following provides a comparison summary of the technical characteristics of each device.

Characteristic	Proposed Device	Predicate Device (K042121)
Baxter SIGMA Spectrum Infusion Pump		
Pump Type	Linear peristaltic pump	Linear peristaltic pump
Routes of Administration	• Intravenous • Arterial • Subcutaneous • Epidural • Irrigation of fluid space	• Intravenous • Arterial • Subcutaneous • Epidural • Irrigation of fluid space • Intrathecal

Characteristic	Proposed Device	Predicate Device (K042121)
AC Power	• Input: 120VAC, 60 Hz / 300 mA • Output (Power Adapter P/N 35727): 9VDC/1200 mA,	• Input: 100VAC - 240VAC, 50-60 Hz / 200 mA • Output (Power Adapter P/N 35714): 9VDC/800 mA
Alarm Volume	Variable at three levels: high, medium and low	Variable at three levels: high, medium and low
Air-In-Line	Air In Line: 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 <50 µL bubbles, at room temperature • Detects >1.5 mL of accumulated air over 15 min., excluding <50 µL bubbles, at 15.5°C (60°F)	Inline Air Detection – Air bubbles of >5/8", alarm if >1 ml over 15 minutes, <50 µL bubbles are not summed
Anti-Free Flow System	Set-based, utilizing IV set slide clamp	Set-based, utilizing IV set slide clamp
Battery Power and Capacity – Standard Battery	• Lithium Ion, minimum 1700 mA/h, 7.4 VDC nominal. • Capacity 8 hrs (at 125 mL/hr at the highest backlight settings) • 12 hr recharge time	• Lithium Ion, 1800 mA/h, 7.2 VDC nominal. • Capacity < 11.5hrs (at 115 mL) at 10 mL/hr, 14 hrs (1750 mL) at 125 mL/hr, 12 hrs (3000mL) at 999 mL/hr with backlight off. • 8 hr. recharge time
Battery Power and Capacity – Wireless Battery (802.11b/g)	• Lithium Ion, minimum 1700 mA/h, 7.4 VDC nominal • Capacity 4 hrs (at 125 mL/hr at the highest backlight settings with wireless communication on) • 16 hr recharge time	N/A - No Wireless Battery Module

Characteristic	Proposed Device	Predicate Device (K042121)
Dose Modes	• mL/hr, mL/kg/min, mL/kg/hr, mL, mL/kg • g/hr, mg/hr, mg/kg/hr, mg/min, mg/kg/min, mg/kg/day, mcg/hr, mg/kg/hr, mcg/min, mcg/kg/min, mcg/kg/day, ng/min, ng/kg/min, grams, grams/kg, grams/m^2, mg, mg/kg, mg/m^2, mcg, mcg/kg, mcg/m^2 • Units/hr, Units/kg/hr, Units/min, Units/kg/min, mUnits/min, mUnits/kg/hr, mUnits /kg/min, Units, Units/kg, Units/m^2 • mEq/hr, mEq/kg/hr, mEq, mEq/kg • mmol/hr, mmol/kg/hr, mmol, mmol/kg	• mL/hr • g/hr, mg/hr, mg/kg/hr, mg/min, mg/kg/min, mcg/hr, mg/kg/hr, mcg/min, mcg/kg/min, ng/min, ng/kg/min • Units/hr, Units/kg/hr, Units/min, Units/kg/min, mUnits/min • mEq/hr, mEq/kg/hr
External Interfaces/ Communications	Bi-directional • IrDA • Additional Asynchronous Serial Port expansion bus available at battery terminals (manufacturer use only) and wireless-enabled battery pack	Bi-directional • IrDA • Additional Asynchronous Serial Port expansion bus available at battery terminals (manufacturer use only)
Flow rate	• 0.5 to 999 mL/hr with 0.1 mL/hr increments from 0.5 to 99.9 mL/hr • 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 • 1 mL/hr increments thereafter
Infusion Modes	• Continuous Primary and Secondary • Multi-Step • Cyclic TPN • Rate Change • Bolus • Amount/Time (Primary/Secondary)	• Continuous Primary and Secondary • Titration • Ramp/Taper • Bolus

Characteristic	Proposed Device	Predicate Device (K042121)
Intended Use/ Indications for Use	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.	The Spectrum and Spectrum with Master Drug Library is intended to be used for the controlled administration of intravenous 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, intrathecal, epidural or irrigation of fluid space. The spectrum is intended to be used in conjunction with legally marketed intravenous administration sets and medications provided by the user. The Spectrum and Spectrum with Master Drug Library is suitable for many user facility applications such as but not limited to hospitals, outpatient care areas, homecare and ambulatory care services. The Spectrum and Spectrum with Master Drug Library is intended to reduce operator interaction through automated programming, thereby helping to reduce errors associated with complex device programming. Parameter programming requires trained healthcare professional confirmation of limits and drug therapy to physician's directive.

Characteristic	Proposed Device	Predicate Device (K042121)
Keep Vein Open (KVO)	At the completion of a primary infusion, the pump will infuse at the KVO rate configured per drug in the Drug Library or the current infusion rate, whichever is lower. The default KVO rate is set at 1 mL/hr, but may be configured to between 0.5 – 50 mL/hr. At the completion of a secondary infusion program with secondary callback enabled, the pump will run at a fixed KVO rate of 1 mL/hr.	KVO rate of either 1 mL/hr or the actual rate, whichever is lower at infusion completion alarm.
Occlusion Pressure	Adjustable: • High (19 ±9 PSI) • Medium (13 ±6 PSI) • Low (6 ±4 PSI)	Adjustable: • High (19 ±9 PSI) • Medium (13 ±6 PSI) • Low (6 ±4 PSI)
Operational Conditions	With Standard Battery • Operating temperature: 60 to 90°F (15.6 to 32.2° C), 20 to 90% relative humidity non-condensing With Wireless Battery Module • Operating temperature: 60 to 80°F (15.6 to 26.7° C), 20 to 90% relative humidity non-condensing	With Standard Battery • Operating temperature: 60 to 90°F (15.6 to 32.2° C), 20 to 90% relative humidity non-condensing N/A - No Wireless Battery Module
Overall Size (Pump)	With Standard Battery • Without IV pole clamp – 5.8" H x 4.2" W x 2.5" D • With standard IV pole clamp – 5.8" H x 6.4" W x 4.7" D With Wireless Battery Module • Without IV pole clamp – 6.3" H x 4.2" W x 2.5" D • With standard IV pole clamp – 6.3" H x 6.4" W x 4.7" D	With Standard Battery • Without IV pole clamp – 5.8" H x 4.2" W x 2.5" D • With standard IV pole clamp – 5.8" H x 6.4" W x 4.7" D N/A - No Wireless Battery Module

Characteristic	Proposed Device	Predicate Device (K042121)
Volumetric Accuracy[1]	Volumetric accuracy at stated flow rates: • 2.0-999 mL/hr ± 5% • 0.5-1.9 mL/hr ± 0.1mL/hr Specified accuracy is maintained on compatible **Baxter Standard IV Sets** for up to 96 hours (maximum 12 liters)	Volumetric accuracy using standard Abbott Sets (now Hospira) • 2-999 mL/hr ± 5% • 0.5-1.9 mL/hr ± 0.1mL/hr
Maximum Allowable pressure while in downstream occlusion	30 PSI	36 PSI
Weight	With Standard Battery • Without IV pole clamp – 25.5 oz. ± 1.0 oz. • With standard IV pole clamp – 33.5 oz. ± 1.0 oz. With Wireless Battery Module • Without IV pole clamp – 26.5 oz. ± 1.0 oz. • With standard IV pole clamp – 34.5 oz. ± 1.0 oz.	• Without IV pole clamp – 24 oz. • With standard IV pole clamp – 32 oz. N/A - No Wireless Battery Module

Characteristic	Proposed Device	Predicate Device (K042121)
Alarms	• AC Applied/Removed • Air Still Detected • Air-In-Line • Bag Near Empty • Battery Alert • Battery Depleted • Battery Missing • Check Flow (unconfirmed) • Clean Load Point #2 • Clock Battery Low • Close Clamp, Reload Set • Close Door, Remove Clamp (on power off) • Door Not Fully Latched • Door Open (Close Roller Clamp) • Downstream Occlusion • Improper Shutdown • Inactivity Alarm • Infusion Complete (Primary, Secondary, Loading Dose and Bolus) • Load Set (based on set loading sequence) • Low Battery • Max Air Detected • PIC Alarm (Errors in Microprocessor) • Reload Set • Remove Clamp (Primary Siphoning Callback) • Slide Clamp Detected • System Error • Upstream Occlusion • Value Entry Timeout (Rate Change Incomplete) • Very Low Battery	• Air-In-Line • Audio • Battery Not Detected • Dead Battery • Downstream Occlusion • Infusion Complete • Inactivity Alarm • In Stop – Load Set • In Stop – Open Slide Clamp • In Stop – Push RUN • Low Battery • Shut Door • Slide Clamp Closed • System Error • Upstream Occlusion

Characteristic	Proposed Device	Predicate Device (K042121)
Master Drug Library Editor		
Drug capacity	Up to 5,000 drugs and 32 care areas	Up to 1,000 drugs and 32 care areas
Available Limits	• Upper Hard Limit • Upper Soft Limit • Starting Rate • Lower Soft Limit • Lower Hard Limit	• Upper Hard Limit • Upper Soft Limit • Starting Rate • Lower Soft Limit • Lower Hard Limit
Security Roles for MDL	• Read-Only Access • Limited Access • Full Access	• Read-Only Access • Limited Access • Full Access
MDL 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 preformed	• Standard 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 preformed

[1]Deviations from Flow Rate Accuracy

The device labeling contains Warning statements that identify deviations in the stated flow rate accuracy and performance limitations for specific system configurations. These system configurations relate to variations of fluid viscosity, fluid temperature, head height or back pressure, or any combination thereof, that exceed stated conditions needed to achieve the device flow rate accuracy and performance claims. In addition, there are specific IV set Warnings that relate to certain design attributes of the set, such as use of sets with vents, burettes, minidrip chambers and backcheck valves, and set materials (i.e., non-DEHP). The Operators Manual contains complete information regarding these Warning statements.

Assessment of Clinical Testing

No clinical testing was performed in support of this premarket notification.

Assessment of Non-Clinical Testing

Non-clinical testing of the Baxter SIGMA Spectrum Infusion Pump with Master Drug Library has been performed against requirements for performance, physical attributes, environmental conditions and safety, and to provide objective evidence that the device intended use is met. Verification was performed through bench testing and assured the following requirement attributes were met:

- Functional and Performance
- System Hardware
- Administration Set Compatibility
- Power
- Environmental and Physical
- Reliability
- System Software
  - User Interface
  - Processing
  - Sensors and Alarms
- Network Interface
  - Wireless Battery Module
  - Serial Communication
- Labeling
- Consensus Standards
  - IEC 60601-1 (1988), "Medical Electrical Equipment, Part 1: General Requirements for Safety" with Amendment 1 (1991) and Amendment 2 (1995)
  - IEC 60601-1-2:2001, " Medical Electrical Equipment-Part 1-2 Edition 2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests with Amendment 1 (2004), Section 36, Deviation per IEC 60601-2-24:1998
  - UL 60601-1 (2003), 1st Edition "Medical Electrical Equipment, Part 1: General Requirements for Safety"
  - CAN/CSA C22.2 No 601.1-M90 (1990), "Medical Electrical Equipment, Part 1: General Requirements for Safety"

- IEC 60601-2-24 (1998), "Medical Electrical Equipment Part 2-24: Particular Requirements for the Safety of Infusion Pumps and Controllers"

- Master Drug Library

In addition to the above, and in consideration of IEC 62366:2007, Medical devices -- Application of usability engineering to medical devices", Baxter conducted a Human Factors evaluation in a simulated environment to ensure that use of the Baxter SIGMA Spectrum Infusion Pump with Master Drug Library would not exhibit use errors that are greater than minimal risk. User needs and intended uses were evaluated through clinical assessment of use, industry literature, labeling evaluation and blood and blood component testing.

Lastly, in complying with the requirements in FDA draft guidance, "Total Product Life Cycle: Infusion Pump – Premarket Notification [510(k)] April 23, 2010", Baxter has developed a Safety Assurance Case to demonstrate that hazardous situations resulting from the design, intended use and reasonably foreseeable misuse of the device have been appropriately mitigated.

Non-clinical testing of the Baxter SIGMA Spectrum Infusion Pump with Master Drug Library met all acceptance criteria, demonstrating that the device is safe and effective for its intended use.

Conclusion:

The Baxter SIGMA Spectrum Infusion Pump with Master Drug Library has been verified and validated against design input requirements, user needs and intended uses. Based on testing and the comparison of design, performance, and intended use, the Baxter SIGMA Spectrum Infusion Pump with Master Drug Library raises no new questions concerning safety and effectiveness and is, thus, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 7, 2014

Baxter Healthcare Corporation
Thomas Sampogna
Senior Director, Regulatory Affairs
32650 N. Wilson Street
Round Lake, Illinois 60073

Re: K133801
Trade/Device Name: Baxter SIGMA Spectrum Infusion Pump with Master Drug Library, Model 35700
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN, PHC
Dated: April 30, 2014
Received: May 1, 2014

Dear Mr. Sampogna:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133801

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.

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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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman
Date: 2014.05.06 17:00:22 -04'00'

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