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

November 30, 2016

Baxter Healthcare
Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K161323
Trade/Device Name: Solution Set for Epidural Use
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: II
Product Code: FPA
Dated: November 15, 2016
Received: November 16, 2016

Dear Mark Job:

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,

Tina Kiang -S

Tina Kiang, Ph.D.
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 below.

510(k) Number *(if known)*
K161323

Device Name
Solution Set for Epidural Use

Indications for Use *(Describe)*
For the administration of fluids from a container into the patient's epidural space with Baxter infusion pumps.

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

November 30, 2016

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IDENTIFICATION OF THE DEVICE:

Common Name: IV Administration Set
Trade Name or Proprietary Name: Solution Set for Epidural Use
Classification Panel: 80 General Hospital
Classification: Set, Administration, Intravascular (21 CFR 880.5440)
Class: Class II
Product Code: FPA

Table 1. Product Code for Solution Set for Epidural Use

Code Number	Name
2E7554	Solution Set for Epidural Use

PREDICATE DEVICE:

Table 2. Predicate Device

Device	Company	Predicate 510(k)	Clearance Date
Bard Epidural Spike Tubing Set	C.R. Bard, Inc. (Bard MedSystems) [a]	K925058	August 3, 1993

[a] Bard MedSystems, a division of C.R. Bard, Inc., was acquired by Baxter in 1993.

DESCRIPTION OF THE DEVICE:

The Solution Set for Epidural Use is a single use disposable device intended for the administration of fluids from a container into the epidural space. The set is used for epidural infusions of fluids (typically analgesic or anesthetic) as an intermittent or continuous infusion to reduce chronic or post-operative pain. The set consists of a non-vented spike, 60 drops per mL drip chamber, minidrip adapter, tubing, fixtured slide clamp, on-off roller clamp, and a male epidural lock connector. The connector is compliant to the provisional AAMI/CN6:2015 *Small-bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications*.

INDICATIONS FOR USE:

For the administration of fluids from a container into the patient's epidural space with Baxter infusion pumps.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed device has equivalent technological characteristics as Baxter's legally marketed epidural set cleared under 510(k) premarket notification K925058 (cleared August 3, 1993). The intended use and function of the proposed device are equivalent to the predicate device. Table 3 is a device comparison table outlining the differences between the predicate and proposed devices.

Table 3. Device Comparison

Features	Predicate Device (K925058): Bard Epidural Spike Tubing Set[a]	Proposed Device: (K161323) Solution Set for Epidural Use[b]	Assessment of Difference
Intended Use	For the administration of fluids from a container into the patient's epidural space.	Same.	N/A
Indications for Use	The Bard Epidural Spike Tubing Set is intended for use with Bard ambulatory infusion pumps to provide epidural delivery of anesthetic or analgesic drugs for periods of up to 96 hours.	For the administration of fluids from a container into the patient's epidural space with Baxter infusion pumps.	The indications for use are being modified from the predicate device to clarify its use and remove reference to a pump that is no longer being marketed. The modification to the indications statement does not impact the safety or efficacy of the proposed device. It represents a clarification only as both devices are intended for the administration of epidural therapy through a disposable solution set, both are intended to administer fluids from a source container to the patient's epidural space, and both are intended for pump administration. The specific pump compatibility information and duration of use is referenced in the product labeling for the proposed device.
Sterile	Yes	Same	N/A
Non-Pyrogenic	Yes	Same	N/A
Single Use	Yes	Same	N/A
FLUID PATH MATERIALS:			
Non-Vented Spike	Acrylonitrile Butadiene Styrene	Same	N/A

Table 3. Device Comparison

Features	Predicate Device (K925058): Bard Epidural Spike Tubing Set[a]	Proposed Device: (K161323) Solution Set for Epidural Use[b]	Assessment of Difference
Drip Chamber	N/A	Polyvinyl Chloride	The predicate device does not have a drip chamber. A drip chamber is included on the proposed device for the end user to verify drops are falling within the drip chamber. Design control activities confirmed there was no impact to the safety or effectiveness of the device due to this change.
Minidrip Adapter	N/A	Synthetic Polyisoprene and Stainless Steel	The predicate device does not have minidrip adapter. A minidrip adapter is included on the proposed device to allow more accurate visibility of drops falling, since epidural infusion tends to be towards the lower side of infusion rates. Design control activities confirmed there was no impact to the safety or effectiveness of the device due to this change.
Tubing	Silicone and Polyvinyl Chloride	Polyvinyl Chloride	The predicate device is used with a Bard pump and has a separate tubing segment made of silicone that interfaces with that pump. The proposed device utilizes PVC tubing throughout the device. A section of this PVC tubing interfaces with Baxter pumps. This same PVC tubing is used in other Baxter IV sets cleared for use with the same Baxter pumps with which the proposed device will be used. Design control activities confirmed there was no impact to the safety or effectiveness of the device due to this change.

Table 3. Device Comparison

Features	Predicate Device (K925058): Bard Epidural Spike Tubing Set[a]	Proposed Device: (K161323) Solution Set for Epidural Use[b]	Assessment of Difference
Anti-Siphon Valve	Polycarbonate and Silicone	N/A	Not present. The proposed device does not have an anti-siphon valve. This valve has been removed as it was a design specifically for the Bard pump, and to align with the design of other currently marketed Baxter administration sets. Design control activities confirmed there was no impact to the safety or effectiveness of the device due to this change.
Two-Piece Male Luer Lock Connector	Polymethyl Methacrylate	N/A	Not present. The proposed device has an epidural lock connector instead.
One-Piece Male Epidural Lock Connector	N/A	Acrylonitrile Butadiene Styrene	The epidural lock is made of the same material type as the Luer lock's body in K142011, but differs in dimensions due to the dimensional requirements of AAMI/CN6:2015. Design control activities confirmed there was no impact to the safety or effectiveness of the device due to this change.

[a] Bard MedSystems, a division of C.R. Bard, Inc., was acquired by Baxter in 1993.

[b] Similar IV sets have been previously cleared in 510(k) premarket notification K142011. These sets have all the same components as the proposed device, the only difference being the epidural lock connector, which is the same material type as the K142011 Luer lock connector, but just differs in dimension due to the dimensional requirements of AAMI/CN6:2015.

DISCUSSION OF NONCLINICAL TESTS:

Baxter Healthcare Corporation conducts risk analyses and design verification tests based on the results of these analyses. All test results meet their acceptance criteria and support that the proposed device is appropriately designed for its intended use.

Performance Data:

The following bench tests were conducted to evaluate the functional performance of the Solution Set for Epidural Use:

- Drop Volume Test
- Cannula Pull Out Test
- Spike Insertion Test
- Spike Removal Test
- Roller Clamp Force Test
- Roller Clamp Shut-Off and Tubing Leak Test
- Slide Clamp Shut Off Test
- Solvent Bond Tensile Strength Test (for all bonds)
- Solvent Bond Air/Water Pressure Test (for all bonds)
- AAMI/CN6:2015 Connector Tests on Male Epidural Lock Connectors
- Pump Tests
    - Flow Rate Accuracy
    - Upstream/Downstream Occlusion
    - Tubing Crimping/Flexion When Used with Infusion Pumps

All tests met the acceptance criteria.

Biocompatibility:

All patient-contacting components meet the category of External Communicating Device, Indirect Blood Path, Prolonged Duration in accordance with ISO 10993-1 and FDA Blue Book Memorandum #G95-1 *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,"* as recommended in the IV administration sets guidance, *Guidance for Industry and FDA Staff: Intravascular Administration Sets Premarket Notification Submissions [510(k)]*.

Biocompatibility assessment has been conducted on a representative final, finished device for all materials of the Solution Set for Epidural Use. The following tests were conducted as part of the biocompatibility testing:

- Cytotoxicity
- Systemic Toxicity
- Irritation/Intracutaenous Reactivity
- Sensitization
- Hemocompatibility
- USP Physiochemical
- USP Material Mediated Pyrogen

Sterility:

The Solution Set for Epidural Use is sterilized with gamma radiation. The Minimum Sterilizing Dose (MSD) required to provide a 10^{-6} Sterility Assurance Level (SAL) for this (sub) category was established and validated at the manufacturing facility using Method 1 as described in ANSI/AAMI/ISO 11137-2 Sterilization of Health Care Products – Radiation – Part 2: Establishing the Sterilization Dose.

This product is labeled "Sterile, nonpyrogenic." Package verification testing is based on Visual Inspection, ASTM F88 Seal Strength, and ASTM F2096 Bubble Leak.

Shelf-Life:

Baxter has provided aging tests to support a shelf-life claim of one (1) year. Baxter intends to perform testing to expand the shelf-life up through a period of five (5) years.

CONCLUSION:

The nonclinical data support the substantial equivalence of the proposed device and demonstrate that the proposed device performs comparably to the predicate device that is legally marketed for the same intended use.