November 23, 2021

Baxter Healthcare Corporation
Jeffrey Thompson
Manager, Regulatory Affairs
25212 West Illinois Route 120
Round Lake, Illinois 60073

Re: K211649
Trade/Device Name: PCEA Syringe Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: PWH
Dated: October 20, 2021
Received: October 25, 2021

Dear Jeffrey Thompson:

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,

For Payal Patel
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211649

Device Name
PCEA Syringe Set

Indications for Use *(Describe)*
For the administration of anesthetics and/or analgesics from a syringe into the patient's epidural space through an epidural access device.

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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K211649

510(k) Summary

OWNER:

Baxter Healthcare Corporation
25212 W. IL Route 120
Round Lake, Illinois 60073

CONTACT PERSON:

Jeffrey E. Thompson
Manager, Regulatory Affairs
25212 W. IL Route 120
Round Lake, Illinois 60073
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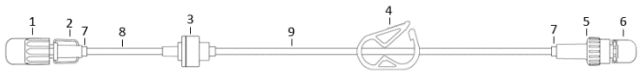
Date Preparation: November 23, 2021

SUBJECT DEVICE:

Trade/Device Name: PCEA Syringe Set
Classification Panel: 80 General Hospital
Regulation Number: 21 CFR 880.5440
Common Name: Administrations Sets with Neuraxial Connectors
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: PWH

Table 1. PCEA Syringe Set Configuration

Code #	Device Description	
2P3334	PCEA Syringe Set with Anti-Siphon Valve, 85” (216 cm), Vol 2.2 mL 	1: Female NRFit Cap 2: Female NRFit Lock 3: Anti-Siphon Valve 4: On-Off Clamp 5: Male NRFit Lock 6: Male NRFit Cap 7: Non-DEHP Tube Bushing 8,9: Non-DEHP Tube

PREDICATE DEVICE:

Table 2: Predicate Device

Device	Company	Predicate 510(k)	Clearance Date
CADD Yellow Extension Sets with NRFit™ connector	Smiths Medical ASD, Inc.	K162219	July 20, 2017

REASON FOR SUBMISSION:

The basis for this premarket notification is the intent to market a patient controlled epidural analgesia (PCEA) syringe set. The proposed device in this submission is a single-use, disposable device, intended for the administration of anesthetics and/or analgesics from a syringe into the patient's epidural space through an epidural access device.

DESCRIPTION OF THE DEVICE:

The proposed device is a patient controlled epidural analgesia (PCEA) syringe set. It is a single use disposable device intended for the administration of anesthetics and/or analgesics from a syringe into the patient's epidural space through an epidural access device. It is a non-pyrogenic, sterile device that can be directly attached to a syringe.

The PCEA syringe set consists of non-DEHP PVC tubing/bushing, female NRFit cap, female NRFit lock, anti-siphon valve, on-off clamp, male NRFit lock, and male NRFit cap. It is used to administer anesthetics and/or analgesics from a syringe to the patient's epidural space through an epidural access device.

The anti-siphon valve component adds specific functionalities to facilitate the administration of anesthetics and/or analgesics to the patient's epidural access device, as described below:

- Anti-siphon valve: reduces the risk of any inadvertent free flow of solution to the patient. The higher opening pressure does not allow administration of flow into the patient's epidural access device, unless the stipulated pressure is applied. Another safety feature is that the valve does not allow any backflow. This prevention of backflow is achieved through the valve's ability to withstand a counterflow pressure.

INDICATIONS FOR USE:

For the administration of anesthetics and/or analgesics from a syringe into the patient's epidural space through an epidural access device.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed device is substantially equivalent to the predicate device, previously cleared under 510(k) premarket notification K162219 on July 20, 2017. The intended use and function of the proposed device is 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

Feature	Predicate K162219	Subject Device K211649	Assessment of Differences
Indication for Use	CADD Yellow Extension Sets with NRFit™ connectors are designed for use only with CADD Yellow Medication Cassette Reservoirs with NRFit™ connectors for the delivery of regional anesthetics or narcotics.	For the administration of anesthetics and/or analgesics from a syringe into the patient's epidural space through an epidural access device.	Both the proposed and predicate device are intended to deliver similar medications to the patient through NRFit connections. The specified fluid containers for the proposed and predicate devices are different; however, the connections to both fluid containers claim compliance to the same ISO 80369-6 standard ("NRFit"). Design control activities have been conducted and have confirmed that the different technological characteristics of the proposed device does not raise different questions of safety and effectiveness.
Sterility	Sterile; Ethylene Oxide	Sterile; Gamma Irradiation	Both the proposed and predicate devices have been validated to a sterility assurance level (SAL) of $\leq 10^{-6}$ using ISO 11137 for the proposed device and ISO 11135 for the predicate device. The sterilization modalities for the proposed and predicate devices are

Table 3. Device Comparison

Feature	Predicate K162219	Subject Device K211649	Assessment of Differences
			different (gamma irradiation and ethylene oxide, respectively); however, the validated SAL requirement for both devices aligns with the same ANSI/AAMI ST67 standard (Sections 4.2.1 and 4.2.1.1), and the technological differences between the sterilization modalities do not raise questions of safety and effectiveness.
Non-Pyrogenic	Yes	Same	N/A
Single Use	Yes	Same	N/A
Length	90”	85” (216 cm)	The proposed device length is nominally shorter than the predicate device length. Design control activities have been conducted and have confirmed that the different technological characteristics of the proposed device does not raise different questions of safety and effectiveness. Lengths were calculated using nominal values from component and tubing part specifications per Baxter procedure.
Tubing Inner / Outer Diameter	Information not available	Inner Diameter - 1.1 mm Outer Diameter - 2.5 mm	The information is not available for the predicate device. Design control activities have been conducted on the proposed device and have confirmed that if there are different technological characteristics to the predicate device, they would not raise different questions of safety and effectiveness. Tensile strength and leakage were evaluated per ISO 8536-9.

Table 3. Device Comparison

Feature	Predicate K162219	Subject Device K211649	Assessment of Differences
Priming Volume	2.3 mL	2.2 mL	The proposed device priming volume is nominally less than the predicate device priming volume. Design control activities have been conducted and have confirmed that the different technological characteristics of the proposed device does not raise different questions of safety and effectiveness. Priming volume was determined per Baxter test method.
Fluid Path Components/Materials			
Anti-Siphon Valve	Polycarbonate (Housing) Silicone (Membrane)	Same	N/A
Tubing	Polyvinyl Chloride	Same	N/A
Tube Bushing	Not Applicable	Polyvinyl Chloride	The predicate device does not have tube bushings. Design control activities have been conducted and have confirmed that the different technological characteristics of the proposed device does not raise different questions of safety and effectiveness. Biocompatibility assessments were conducted per ISO-10993-1.
Female NRFit Lock	Not Applicable	Copolyester	The predicate device does not have a female NRFit

Table 3. Device Comparison

Feature	Predicate K162219	Subject Device K211649	Assessment of Differences
			lock. Design control activities have been conducted and have confirmed that the different technological characteristics of the proposed device does not raise different questions of safety and effectiveness. Biocompatibility assessments were conducted per ISO-10993-1. Functional performance was evaluated per ISO 80369-6.
Male NRFit Lock	Acrylonitrile Butadiene Styrene	Copolyester	The predicate device does not have the same type of material formulation. Design control activities have been conducted and have confirmed that the different technological characteristics of the proposed device does not raise different questions of safety and effectiveness. Biocompatibility assessments were conducted per ISO-10993-1. Functional performance was evaluated per ISO 80369-6.
Male NRFit Cap	Linear Low Density Polyethylene	Acrylic	The predicate device does not have the same type of material formulation. Design control activities have been conducted and have confirmed that the different technological characteristics of the proposed device does not raise different questions of safety and effectiveness. Biocompatibility assessments were conducted per ISO-10993-1.

DISCUSSION OF NONCLINICAL TESTS:

Baxter Healthcare Corporation conducts risk analyses and design verification tests based on the result 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 (Table 4) were conducted to evaluate the functional performance of the proposed device:

Table 4: Performance Data

Test	Acceptance Criteria
ISO 80369-6 Tests on Male NRFit (Neuraxial Fit) Lock Connector	ISO 80369-6: 2016, Clause 5 (as applicable), ISO 80369-6:2016, Clause 6.1, ISO 80369-6:2016, Clause 6.2, ISO 80369-6:2016, Clause 6.3, ISO 80369-6:2016, Clause 6.4, ISO 80369-6:2016, Clause 6.5, ISO 80369-6:2016, Clause 6.6
ISO 80369-6 Tests on Female NRFit (Neuraxial Fit) Lock Connector	ISO 80369-6: 2016, Clause 5 (as applicable), ISO 80369-6:2016, Clause 6.1, ISO 80369-6:2016, Clause 6.2, ISO 80369-6:2016, Clause 6.3, ISO 80369-6:2016, Clause 6.4, ISO 80369-6:2016, Clause 6.5, ISO 80369-6:2016, Clause 6.6
Tensile Strength Test	ISO 8536-9:2015, Clause 5.3
Leak Test	ISO 8536-9:2015, Clause A.4
Counter Flow Test	ISO 8536-12:2007+A1:2013, Clause A.4
Blocking Performance Test	ISO 8536-12:2007+A1:2013, Clause A.6
Opening Pressure Test	ISO 8536-12:2007+A1:2013, Clause A.7.1 and per Baxter Test Method
Particulate Matter Test	USP Chapter <788>
Clamp Activation Force Test	Per Baxter Test Method
Clamp Shut-Off Test	ISO 8536-14:2018, Clause A.1
Non-DEHP Claim Verification	Per Baxter Test Method (as tested in K161808)

All tests met the acceptance criteria.

Biocompatibility:

Biocompatibility assessments were conducted based on ISO-10993-1, Biological Evaluation of Medical Devices for prolonged contact duration, external communicating device, tissue/bone/dentin, and FDA-2013-D-0350 Guidance for Industry & FDA Staff, Use of ISO 10993-1, "Biological evaluation and medical devices – Part 1: Evaluation and testing within a risk management process, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing", as recommended in the Intravascular Administration Sets guidance, "Guidance for Industry and FDA Staff: Intravascular Administration Sets Premarket Notification Submissions [510(k)]". Biocompatibility assessments include the following assays:

- Cytotoxicity ISO 10993-5
- Sensitization ISO 10993-10
- Intracutaneous (Irritation) Reactivity ISO 10993-10
- Acute Systemic Toxicity ISO 10993-11
- Material Mediated Pyrogen ISO 10993-11
- Genotoxicity ISO 10993-3
- Subacute Systemic Toxicity ISO 10993-11

Based upon the results the device met the designated ISO 10993-1 categorization and is biocompatible and appropriate for the intended use.

Sterility:

The proposed device is sterilized with gamma radiation. The product is in the bioburden (sub) category "General Sets Labeled 'Sterile". 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 as described in ANSI/AAMI/ISO 11137-2, "*Sterilization of health care products - Radiation-Part 2: Establishing the sterilization dose.*" The dose setting method used includes, but is not limited to, Method 1 or VDmax. Generally, the MSDs are between 14.2 – 25.0 kGy. The continued validity of the MSD for this (sub) category is confirmed via periodic dose audit studies. In addition, routine periodic pre-sterilization bioburden testing is performed for each (sub) category. The endotoxin limit is 2.15 EU/device per USP <161>.

Shelf Life:

Baxter has performed aging testing to support a shelf-life claim of 3 (three) years.

CONCLUSION:

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The non-clinical data demonstrate that the subject device is substantially equivalent and performs comparably to the predicate device that is legally marketed for the same intended use.