October 3, 2022

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

Re: K212262
Trade/Device Name: PCA Syringe Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FPA
Dated: September 1, 2022
Received: September 2, 2022

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,

David Wolloscheck, Ph.D.
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)*
K212262

Device Name
PCA Syringe Sets

Indications for Use *(Describe)*
For the administration of fluids from a container into the patient's vascular system through a vascular access device. For use in adult populations only.

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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K212262 510(k) Summary

DATE:

October 3, 2022

OWNER:

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

CONTACT PERSON:

Meaghan Bonn
Principal Specialist, Regulatory Affairs
25212 W. IL Route 120
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Telephone: (224) 270 6470
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IDENTIFICATION OF THE DEVICE:

Trade/Device Name: PCA Syringe Sets
Classification Panel: 80 General Hospital
Regulation Number: 21 CFR 880.5440
Regulation Name: Set, Administration, Intravascular
Regulatory Class: Class II
Product Code: FPA

Table 1. Proposed PCA Syringe Sets Configurations

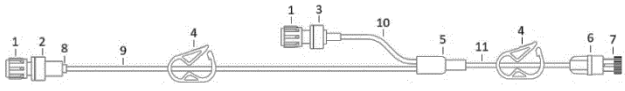
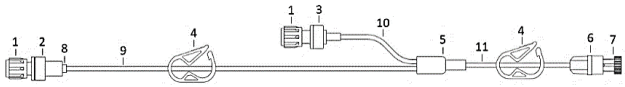
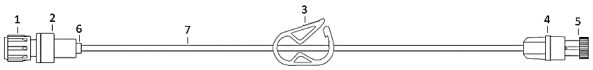
Code #	Device Description	
2P3331	PCA Mini-Volume Syringe Set with Anti-Siphon Valve and Y-Type Connector with Back Check Valve, 74" (188 cm), Vol 1.2 mL 	1: Female Luer Cap 2: Anti-Siphon Valve w/ Female Luer 3: Back Check Valve w/ Female Luer 4: On-Off Clamp 5: Y-Connector 6: Male Luer Lock 7: Male Luer Cap 8: Non-DEHP Tube Bushing

Table 1. Proposed PCA Syringe Sets Configurations

Code #	Device Description	
		9,10,11: Non-DEHP Tube
2P3332	PCA Mini-Volume Syringe Set with Anti-Siphon Valve and Y-Type Connector with Back Check Valve, 98" (249 cm), Vol 1.5 mL 	1: Female Luer Cap 2: Anti-Siphon Valve w/ Female Luer 3: Back Check Valve w/ Female Luer 4: On-Off Clamp 5: Y-Connector 6: Male Luer Lock 7: Male Luer Cap 8: Non-DEHP Tube Bushing 9,10,11: Non-DEHP Tube
2P3333	PCA Mini-Volume Syringe Set with Anti-Siphon Valve, 92" (234 cm), Vol 1.3 mL 	1: Female Luer Cap 2: Anti-Siphon Valve w/ Female Luer 3: On-Off Clamp 4: Male Luer Lock 5: Male Luer Cap 6: Non-DEHP Tube Bushing 7: Non-DEHP Tube

PREDICATE DEVICE:

Table 2: Predicate Device

Device	Company	Predicate 510(k)	Clearance Date
Clearlink Luer Activated Valve, Clearlink System Non-DEHP Catheter Extension Sets	Baxter Healthcare Corporation	K112893 (model 2N8374)	October 18, 2011

REASON FOR SUBMISSION:

The basis for this premarket notification is the intent to market patient controlled analgesia (PCA) syringe sets. The proposed devices in this submission are single-use, disposable devices, intended for the administration of fluids from a container into the patient's vascular system through a vascular access device.

DESCRIPTION OF THE DEVICE:

The proposed devices are patient controlled analgesia (PCA) syringe sets. They are single use disposable devices intended for the administration of fluids from a container into the patient's vascular system through a vascular access device. They are non-pyrogenic, sterile devices that can be directly attached to a syringe.

The PCA syringe sets consist of non-DEHP PVC tubing/bushing, female luer cap, anti-siphon valve with female luer, on-off clamp(s), male luer lock, male luer cap, back check valve with female luer (2P3331 and 2P3332 only), and y-connector (2P3331 and 2P3332 only). They are used to administer analgesics from a syringe to the patient IV access device (2P3331 and 2P3332 only) or from a syringe to a primary administration set (2P3333 only); and are also used to administer fluids from a container at the y-type connector (2P3331 and 2P3332 only).

The anti-siphon valve and back check valve components add specific functionalities to facilitate the administration of fluid to the patient's vascular 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 vascular 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.

- Back check 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 fluids from a container into the patient's vascular system through a vascular access device. For use in adult populations only.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed devices are substantially equivalent to the predicate device, previously cleared under 510(k) premarket notification K112893 on October 18, 2011. The intended use and function of the proposed devices 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

Features	Predicate Device Cleared under K112893 (Model 2N8374)	Proposed Devices	Assessment of Differences
Intended Use	For use with a vascular access device for the administration of drugs and solutions. The Clearlink Luer Activated Valve is an in-line injection site, which can be connected to the standard male Luer adapters (e.g., syringes or sets) for continuous or intermittent fluid administration or the withdrawal of fluid.	For the administration of fluids from a container into the patient's vascular system through a vascular access device.	Same Minor rewording of the Intended Use statement has been made to better align with 21 CFR 880.5440 and for the purpose of streamlining the information provided to the user. The general purpose of the device and its function remain unchanged. The minor rewording of the Intended Use statement does not raise different questions of safety and effectiveness.
Indications for Use	For use with a vascular access device for the administration of drugs and solutions. The Clearlink Luer Activated Valve is an in-line injection site, which can be connected to the standard male Luer adapters (e.g., syringes or sets) for continuous or intermittent fluid administration or the withdrawal of fluid.	For the administration of fluids from a container into the patient's vascular system through a vascular access device. For use in adult populations only.	Same Minor rewording of the Intended Use statement has been made to better align with 21 CFR 880.5440 and for the purpose of streamlining the information provided to the user. This minor modification does not alter the disease or condition the device will diagnose, treat, prevent, cure/mitigate, or the patient population for which the device is intended to be used. In addition, the minor rewording does not reflect a different anatomical site from which a disease state or population may be inferred. The minor rewording of the Intended Use statement does not raise different questions of safety and effectiveness.
Regulation Number	21 CFR 880.5440	Same	N/A
Product Code	FPA	Same	N/A

Table 3. Device Comparison

Features	Predicate Device Cleared under K112893 (Model 2N8374)	Proposed Devices	Assessment of Differences
Sterile	Gamma Radiation	Same	N/A
Sterility Assurance Level (SAL)	10^{-6}	Same	N/A
Non-Pyrogenic	Yes	Same	N/A
Single Use	Yes	Same	N/A
Length	8.2" (21 cm)	74'' (188 cm) - 98'' (249 cm)	The predicate device comparatively has a shorter length than all of the proposed devices. The proposed devices offer sets with different lengths, allowing the clinician to select the appropriate one for the intended therapy. For different therapies, clinicians might require sets with longer lengths, to ensure delivery of solutions without excessive manipulation of the set. Design control activities have been conducted and have confirmed that the different technological characteristics of the proposed devices do not raise different questions of safety and effectiveness.
Tubing Inner / Outer Diameter	0.039" (0.99 mm) / 0.089" (2.26 mm)	0.0315" (0.8 mm) / 0.0866" (2.2 mm)	The proposed devices tubing inner / outer diameters are nominally less than the predicate device tubing inner / outer diameter. 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	0.5 mL	1.2 mL - 1.5 mL	Due to longer tubing lengths, the priming volumes of the

Table 3. Device Comparison

Features	Predicate Device Cleared under K112893 (Model 2N8374)	Proposed Devices	Assessment of Differences
			proposed devices are larger than the predicate device. 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.
Fluid Path Components/Materials			
Anti-Siphon Valve	Not Applicable	Polymethyl methacrylate (Acrylic) [Female Luer and Tube Port] Silicone (Membrane) (2P3331, 2P3332, 2P3333)	The predicate device does not have an anti-siphon valve. Design control activities have been conducted and have confirmed that the different technological characteristics of the proposed devices do not raise different questions of safety and effectiveness
Back Check Valve	Not Applicable	Polymethyl methacrylate (Acrylic) [Female Luer and Tube Port] Silicone (Membrane) (2P3331, 2P3332)	The predicate device does not have a back check valve. Design control activities have been conducted and have confirmed that the different technological characteristics of the proposed devices do not raise different questions of safety and effectiveness
Tubing	Polyvinyl Chloride (2N8374)	Same (2P3331, 2P3332, 2P3333)	N/A
Tube Bushing	Not Applicable	Polyvinyl Chloride	The predicate device does not have a tube bushing. Design control activities have been

Table 3. Device Comparison

Features	Predicate Device Cleared under K112893 (Model 2N8374)	Proposed Devices	Assessment of Differences
		(2P3331, 2P3332, 2P3333)	conducted and have confirmed that the different technological chara cteristics of the proposed device do not raise different questions of safety and effectiveness.
Y-Connector	Not Applicable	Acrylonitrile Butadiene Styrene (2P3331, 2P3332)	The predicate device does not have a y-connector. Design control activities have been conducted and have confirmed that the different technological chara cteristics of the proposed devices do not raise different questions of safety and effectiveness.
Male Luer Lock	Acrylonitrile Butadiene Styrene (2N8374)	Same (2P3331, 2P3332, 2P3333)	N/A
Male Luer Cap	Polypropylene (2N8374)	High Density Polyethylene (Cap) Hydrophobic Filter, Acrylic (W/Non-Woven Nylon Substrate) (Filter Membrane) (2P3331, 2P3332, 2P3333)	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 devices does not raise different questions of safety and effectiveness.

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 devices are appropriately designed for their intended use.

Performance Data:

The following bench tests (Table 4) were conducted to evaluate the functional performance of the proposed devices:

Table 4. Performance Data

Test	Acceptance Criteria
ISO 80369-7 Tests on Male Luer Lock Connector	ISO 80369-7:2016, Clause 5 (as applicable), ISO 80369-7:2016, Clause 6.1, ISO 80369-7:2016, Clause 6.2, ISO 80369-7:2016, Clause 6.3, ISO 80369-7:2016, Clause 6.4, ISO 80369-7:2016, Clause 6.5, ISO 80369-7:2016, Clause 6.6
ISO 80369-7 Tests on Female Luer Lock Connector	ISO 80369-7: 2016, Clause 5 (as applicable), ISO 80369-7:2016, Clause 6.1, ISO 80369-7:2016, Clause 6.2, ISO 80369-7:2016, Clause 6.3, ISO 80369-7:2016, Clause 6.4, ISO 80369-7:2016, Clause 6.5, ISO 80369-7:2016, Clause 6.6
Tensile Strength Test	BS EN ISO 8536-9:2015, Clause 5.3
Leak Test	BS EN ISO 8536-9:2015, Clause A.4
Counter Flow Test	BS ISO 8536-12:2007+A1:2013, Clause A.4
Blocking Performance Test	BS ISO 8536-12:2007+A1:2013, Clause A.6
Opening Pressure Test (Back Check Valve and Anti-Siphon Valve)	BS 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	Activation force ≤50N
Clamp Shut-Off Test	BS EN 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, indirect blood path, 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
- Systemic Toxicity (acute and repeat dose) ISO 10993-11
- Material Mediated Pyrogen ISO 10993-11
- Genotoxicity ISO 10993-3
- Hemolysis ISO 10993-4

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. Bacterial endotoxins tests were conducted in conformance to USP <85>. The endotoxin limit is 20 EU/device per USP <161>. In addition, routine periodic pre-sterilization bioburden testing is performed for each (sub) category. The sterilization process for the proposed devices was established in accordance with ANSI/AAMI/ISO 11137-1, "*Sterilization of health care products-Radiation-Part 1; Requirements for development, validation and routine control of a sterilization process for medical devices*."

Shelf Life:

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

Microbial Ingress Testing:

Baxter has conducted testing on all the potential points of microbial entry into the sterile fluid pathway of the proposed devices. The potential microbial entry points consist of male and female Luer connector sites. The Luer connector sites were tested following Baxter's testing strategy (as previously cleared under K180739 (cleared on May 28, 2019)) of challenging the connections during simulated clinical use to ensure the absence of microbial ingress to the sterile fluid path. All test results met their acceptance criteria and support that the proposed devices are appropriately designed for their intended use.

CONCLUSION:

The non-clinical data demonstrate that the subject devices are substantially equivalent and perform comparably to the predicate device that is legally marketed for the same intended use.