June 18, 2021

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

Re: K210430
Trade/Device Name: Intravascular Extension Set (Light Resistant Extension Set)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: May 11, 2021
Received: May 21, 2021

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,

CAPT Alan M. Stevens
Acting 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)*

K210430

Device Name
Intravascular (IV) Extension Set (Light Resistant Extension Set)

Indications for Use *(Describe)*
For the administration of fluids from a container into a patient's vascular system through a vascular 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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Section 5. 510(k) Summary

February 10, 2021

OWNER:

Baxter Healthcare Corporation
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Deerfield, Illinois 60015

CONTACT PERSON:

Meaghan Bonn
Senior Specialist, Regulatory Affairs
25212 W. Illinois Route 120
Round Lake, IL 60073
Telephone: (224) 270 6470

IDENTIFICATION OF THE DEVICE:

Trade/Device Name: Intravascular Extension Set (Light Resistant Extension Set)
Classification Panel: 80 General Hospital
Regulation Number: 21 CFR 880.5440
Regulation Name: Set, Administration

Regulatory Class: Class II
Product Code: FPA

Table 1. Proposed IV Extension Set Configuration

Code #	Device Description	
2N3363	Light Resistant Micro-Volume Extension Set, 59” (150 cm), Vol 0.47 mL 	1: Non-Vented Cap for Female Luer 2: Female Luer Lock 3: Notch Clamp 4: Light Resistant Microbore Tubing 5: Male Luer Lock 6: Filter Vented Cap for Male Luer

PREDICATE DEVICE:

Table 2. Predicate Device

Device	Company	Predicate 510(k)	Clearance Date
Intravascular Extension Sets and Accessories	Baxter Healthcare Corporation	K192366 (Model 2N3380)	July 20, 2020

REASON FOR SUBMISSION:

The basis for this premarket notification is the intent to market an Intravascular (IV) Extension Set (Light Resistant Extension Set). The proposed device is a single use disposable device, 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 device consists of an IV Extension Set (Light Resistant Extension Set). It is a single use disposable, non-pyrogenic, sterile device intended for the administration of fluids from a container into the patient's vascular system. This IV extension set can be directly attached to a syringe but also used as an extension set to a primary set that is connected to a syringe (primarily to add length). See Figure 1 and Figure 2 for the clinical use set ups for the proposed device.

The Light Resistant Extension Set consists of non-DEHP (<0.1% DEHP) PVC tubing, a notch clamp, female Luer, non-vented cap for female Luer, male Luer, and filter vented cap for male Luer. It is used to administer fluids from a syringe into the patient's vascular system through a vascular access device, specifically fluids/drugs sensitive to light to the patients of all ages ranges – neonatal, pediatric, and adult.

Figure 1. Clinical Use Set Up of Proposed Device when used directly with a Syringe as a Primary Syringe Set

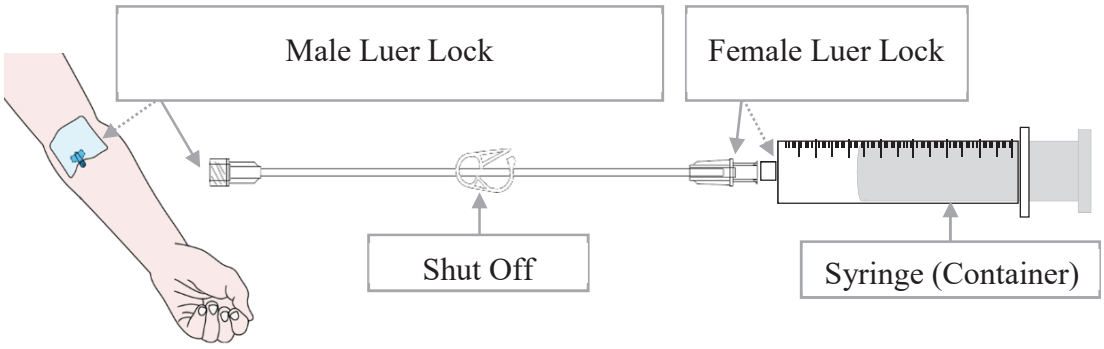
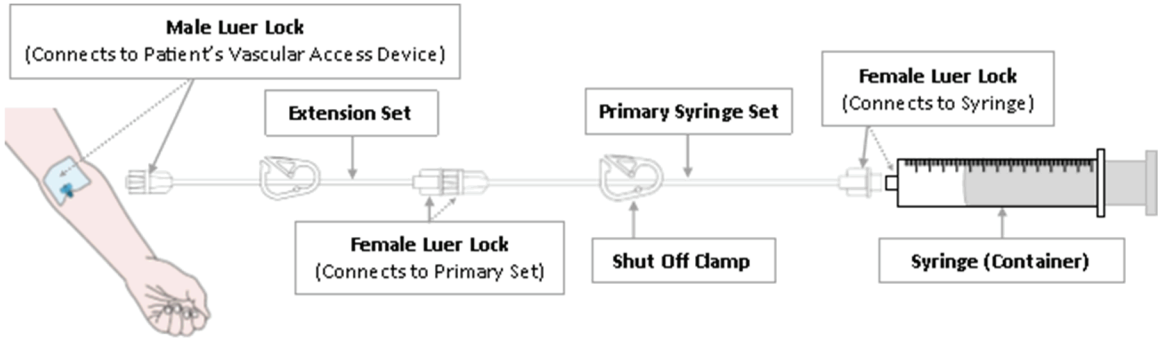


Figure 2. Clinical Use Set Up of Proposed Device when used as an Extension to a Primary Syringe Set



INDICATIONS FOR USE:

For the administration of fluids from a container into the patient's vascular system through a vascular access device.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed device is substantially equivalent to the predicate device (model 2N3380), previously cleared under 510(k) premarket notification K192366 on July 20, 2020. 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

Features	Predicate Device Cleared under K192366 (2N3380)	Proposed Device	Assessment of Differences
Intended Use	For the administration of fluids from a container into the patient's vascular system through a vascular access device	Same	N/A
Indication for Use	For the administration of fluids from a container into the patient's vascular system through a vascular access device.	Same	N/A

Table 3. Device Comparison

Features	Predicate Device Cleared under K192366 (2N3380)	Proposed Device	Assessment of Differences
Regulation Number	21 CFR 880.5440	Same	N/A
Product Code	FPA	Same	N/A
Sterile	Yes	Same	N/A
Non-Pyrogenic	Yes	Same	N/A
Single Use	Yes	Same	N/A
Length	59” (150cm) (2N3380)	Same	N/A
Fluid Path Components/Materials			
Tubing	Polyvinyl Chloride (2N3380)	Same	N/A
Female Luer Lock	Polymethyl methacrylate (Acrylic) (2N3380)	Same	N/A
Male Luer Lock	Acrylonitrile Butadiene Styrene (2N3380)	Same	N/A
Filter Vented Cap for Male Luer	High Density Polyethylene (Cap) Hydrophobic Filter, Acrylic (W/Non-Woven Nylon Substrate) (Filter Membrane) (2N3380)	Same	N/A

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 80369-7 Luer Tests on male Luer Lock Connector	ISO 80369-7:2016, Clause 6.1.2 or 6.1.3, ISO 80369-7:2016, Clause 6.2, ISO 80369-7:2016, Clause 6.3, ISO 80369-20:2015, Annex E, ISO 80369-7:2016, Clause 6.4, ISO 80369-7:2016, Clause 6.5, ISO 80369-7:2016, Clause 6.6, ISO 80369-7:2016, Clause 5
ISO 80369-7 Luer Tests on female Luer Lock Connector	ISO 80369-7:2016, Clause 6.1.2 or 6.1.3, ISO 80369-7:2016, Clause 6.2, ISO 80369-7:2016, Clause 6.3, ISO 80369-20:2015, Annex E, ISO 80369-7:2016, Clause 6.4, ISO 80369-7:2016, Clause 6.5, ISO 80369-7:2016, Clause 6.6, ISO 80369-7:2016, Clause 5
Tensile Strength Test	BS EN ISO 8536-9, Clause 5.3
Leak Test	BS EN ISO 8536-9: 2015, Section A.4
Notch Clamp Activation Force Test	Per Baxter Test Method
Notch Clamp Shut-Off Test	Per Baxter Test Method
Non-DEHP Claim Verification (< 0.1% DEHP)	Per Baxter Test Method (as tested in K161808)
Particulate Matter Test	USP 788
Light Transmissivity Test	Per Baxter Test Method

All tests met the acceptance criteria.

Biocompatibility:

Biocompatibility assessments were conducted based on ISO-10993-1, Biological Evaluation of Medical Devices for prolonged duration, external communicating device, indirect blood path and FDA-2013-D-0350 Guidance for Industry and FDA Staff, "*Use of International Standard ISO-10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*,'" as recommended in the Intravascular Administration Sets guidance, "*Guidance for Industry and FDA Staff: Intravascular Administration Sets Premarket Notification Submissions [510(k)]*." Biocompatibility assessments were conducted on a worst case/representative final, finished device for all fluid path materials of the proposed device. The following tests were conducted as part of the biocompatibility assessment for the proposed device:

- Cytotoxicity ISO 10993-5
- Sensitization ISO 10993-10
- Intracutaneous (Irritation) Reactivity ISO 10993-10
- Systemic Toxicity (acute and repeat dose) ISO 10993-11
- Materials Mediated Pyrogen ISO 10993-11
- Hemolysis ISO 10993-4 and ASTMF756

Based upon the results of the data supports the ISO 10993-1 categorization of external communicating device, indirect blood path, prolonged contact duration. The proposed device is biocompatible and appropriate for its 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.

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 device (per Baxter test method - as tested in K192366). The potential microbial entry points consist of male and female Luer connector sites. All test results meet their acceptance criteria and support that the proposed device is appropriately designed for its intended use.

CONCLUSION:

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.