July 20, 2020

Baxter Healthcare Corporation
Gary Chumbimune
Associate Director, Regulatory Affairs
32650 N. Wilson Road
Round Lake, Illinois 60073

Re: K192366
Trade/Device Name: Intravascular Extension Sets and Accessories
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA, FPB
Dated: June 16, 2020
Received: June 19, 2020

Dear Gary Chumbimune:

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
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192366

Device Name

Intravascular Extension Sets and Accessories

Indications for Use *(Describe)*

For the administration of fluids from a container into the 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.

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Baxter

510(k) Summary-K192366

July 20, 2020

OWNER:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

CONTACT PERSON:

Gary Chumbimune
Associate Director, Regulatory Affairs
32650 N. Wilson Road
Round Lake, IL 60073
Telephone: (224) 270 3312
Fax: (224) 270 4119

IDENTIFICATION OF THE DEVICE:

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

Table 1. Proposed IV Extension Set Configurations

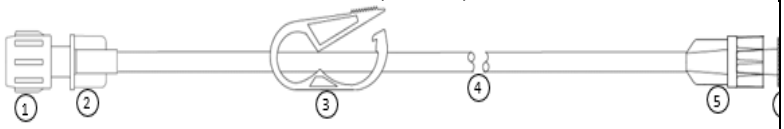
Code #	Device Description	
2N3354	Micro-Volume Extension Set, 79" (200 cm), Vol 0.47 mL 	1: Non-Vented Cap 2: Female Luer Lock 3: Notch Clamp 4: Tubing 5: Male Luer Lock 6: Male Luer Cap

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Table 1. Proposed IV Extension Set Configurations

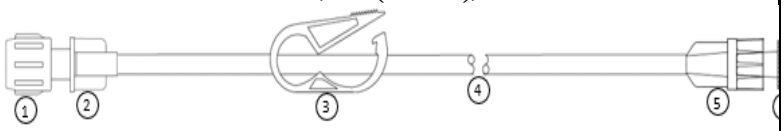
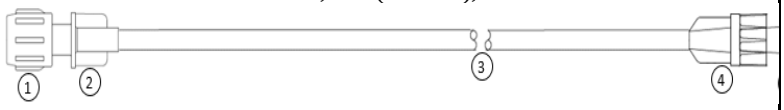
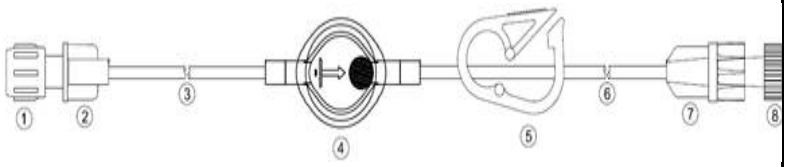
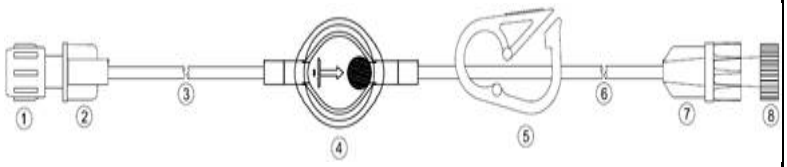
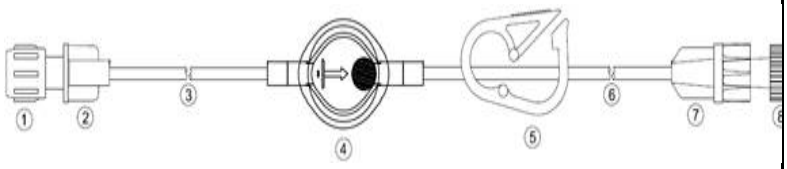
Code #	Device Description	
2N3380	Micro-Volume Extension Set, 59” (150 cm), Vol 0.40 mL 	1: Non-Vented Cap 2: Female Luer Lock 3: Notch Clamp 4: Tubing 5: Male Luer Lock 6: Male Luer Cap
2N3358	Micro-Volume Extension Set, 59” (150 cm), Vol 0.40 mL 	1: Non-Vented Cap 2: Female Luer Lock 3: Tubing 4: Male Luer Lock 5: Male Luer Cap
2N3357	Micro-Volume Extension Set with 0.2 µm Filter, 79” (200 cm), Vol 0.88 mL 	1: Non-Vented Cap 2: Female Luer Lock 3, 6: Tubing 4: 0.2µm Filter 5: Notch Clamp 7: Male Luer Lock 8: Male Luer Cap
2N3382	Micro-Volume Extension Set with 0.2 µm Filter, 59” (150 cm), Vol 0.75 mL 	1: Non-Vented Cap 2: Female Luer Lock 3, 6: Tubing 4: 0.2µm Filter 5: Notch Clamp 7: Male Luer Lock 8: Male Luer Cap
2N3386	Micro-Volume Catheter Extension Set with 0.2 µm Filter, 10” (25 cm), Vol 0.44 mL 	1: Non-Vented Cap 2: Female Luer Lock 3, 6: Tubing 4: 0.2µm Filter 5: Notch Clamp 7: Male Luer Lock 8: Male Luer Cap
2N3355	Mini-Volume Extension Set, 59” (150 cm), Vol 0.91 mL 	1: Non-Vented Cap 2: Female Luer Lock 3: Notch Clamp 4: Tubing

Table 1. Proposed IV Extension Set Configurations

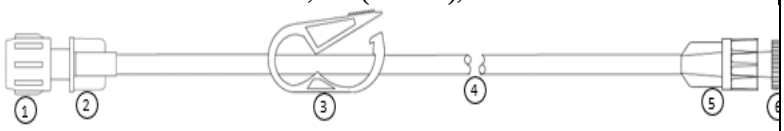
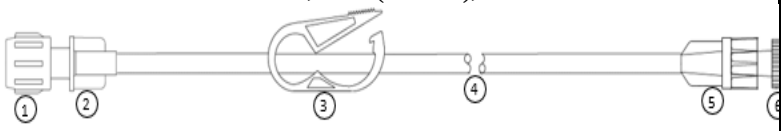
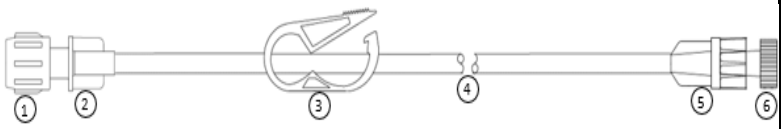
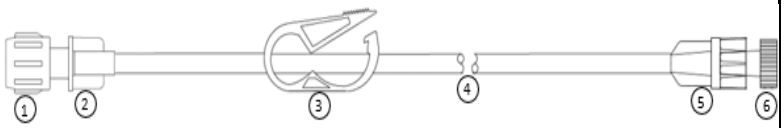
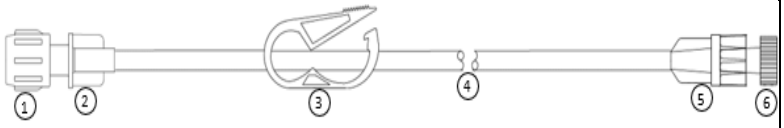
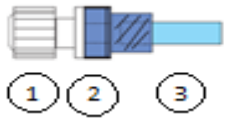
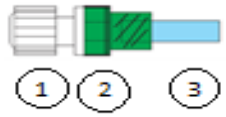
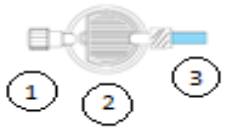
Code #	Device Description	
		5: Male Luer Lock 6: Male Luer Cap
2N3356	Mini-Volume Extension Set, 79" (200 cm), Vol 1.1 mL 	1: Non-Vented Cap 2: Female Luer Lock 3: Notch Clamp 4: Tubing 5: Male Luer Lock 6: Male Luer Cap
2N3359	Mini-Volume Extension Set, 118" (300 cm), Vol 1.4 mL 	1: Non-Vented Cap 2: Female Luer Lock 3: Notch Clamp 4: Tubing 5: Male Luer Lock 6: Male Luer Cap
2N3360	Polyethylene (PE) Lined Micro-Volume Extension Set, 59" (150 cm), Vol 0.40 mL 	1: Non-Vented Cap 2: Female Luer Lock 3: Notch Clamp 4: PE-Lined microbore Tube (Tri-Layer Tubing) 5: Male Luer Lock 6: Male Luer Cap
2N3361	Polyethylene (PE) Lined Micro-Volume Extension Set, 79" (200 cm), Vol 0.47 mL 	1: Non-Vented Cap 2: Female Luer Lock 3: Notch Clamp 4: PE-Lined microbore Tube (Tri-Layer Tubing) 5: Male Luer Lock 6: Male Luer Cap
2N3362	Polyethylene (PE) Lined Mini-Volume Extension Set, 118" (300 cm), Vol 1.6 mL 	1: Non-Vented Cap 2: Female Luer Lock 3: Notch Clamp 4: PE-Lined microbore Tube (Tri-Layer Tubing) 5: Male Luer Lock 6: Male Luer Cap

Table 2. Proposed IV Set Accessories

Code #	Device Description	
2N3364	Anti-Siphon Valve, Vol 0.24 mL 	1: Non-Vented Cap to Female Luer 2: Anti-Siphon Valve 3: Touch Contamination Protector
2N3365	Back Check Valve, Vol 0.28 mL 	1: Non-Vented Cap to Female Luer 2: Back Check Valve 3: Touch Contamination Protector
2N3368	Air-Eliminating 1.2 µm Solution Filter, Vol 0.80 mL 	1: Non-Vented Cap to Female Luer 2: 1.2 µm Filter 3: Touch Contamination Protector

PREDICATE DEVICE:

Table 3. Predicate Device

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

REASON FOR SUBMISSION:

The basis for this premarket notification is the intend to market Intravascular (IV) Extension Sets and Accessories. 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 consist of IV Extension sets and IV set accessories. They are single use disposable devices intended for the administration of fluids from a container into the patient's vascular system. They are non-pyrogenic, sterile devices that can be used with or without a syringe.

The extension sets consist of PVC tubing or polyethylene lined PVC tubing, a notch clamp, female luer, non-vented cap, male luer, and filter vented cap. They are used to administer solutions, drugs, antibiotics, lipids to the patient.

The accessories consists of an anti-siphon valve, back check valve, and 1.2 µm Filter. They attach to the proposed sets to add a specific feature to facilitate the administration of fluid when used with a syringe. The anti-siphon valve reduces the risk of free flow from the syringe and backflow into the primary infusion line. The back check valve prevents backflow into the primary infusion line. The 1.2 µm Filter prevents particulate matter and eliminates air bubbles.

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 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 are equivalent to the predicate device.

Table 4 is a device comparison table outlining the differences between the predicate and proposed devices.

Table 4. Device Comparison

Features	Predicate Device Cleared under K112893	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,	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

Table 4. Device Comparison

Features	Predicate Device Cleared under K112893	Proposed Devices	Assessment of Differences
	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.		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.
Indication 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.	Same Minor rewording of the Indications for 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.
Sterile	Yes	Same	N/A
Non-Pyrogenic	Yes	Same	N/A
Single Use	Yes	Same	N/A
Fluid path Components/Materials			
Anti-Siphon Valve	Not Applicable	Polymethyl methacrylate (Acrylic) [Female and Male Luer] Silicone (Membrane)	The predicate device does not have an anti-siphon check valve. Design control activities have been conducted and have confirmed that the different technological characteristics of the proposed devices do not raise

Table 4. Device Comparison

Features	Predicate Device Cleared under K112893	Proposed Devices	Assessment of Differences
		(2N3364)	different questions of safety and effectiveness
Back Check Valve	Not Applicable	Polymethyl methacrylate (Acrylic) [Female and Male Luer] Silicone (Membrane) (2N3365)	The predicate device does not have a 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
0.2 µm Filter	Not Applicable	Polymethyl methacrylate (Acrylic) [Housing] Polyvinylidene fluoride (Air Vent Membrane) Polyethersulfone (Solution Membrane) (2N3382, 2N3357, 2N3386)	The predicate device does not have a 0.2 µm Filter. These materials have been used in another Baxter cleared device (cleared in K113227, 12/08/11) with the same/similar intended use and with the same type and duration of contact. 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.
Air-Eliminating 1.2 µm Solution Filter	Not Applicable	Polymethyl methacrylate (Acrylic) [Housing] Polytetrafluoroethylene (Air Vent Membrane) Polyethersulfone (Solution Membrane)) (2N3368)	The predicate device does not have a 1.2 µm Filter. 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 (2N3358, 2N3380, 2N3354, 2N3382, 2N3357, 2N3355, 2N3356, 2N3359, 2N3386)	N/A

Table 4. Device Comparison

Features	Predicate Device Cleared under K112893	Proposed Devices	Assessment of Differences
Tri-Layer Tubing	Not Applicable	Low-Density Polyethylene Ethylene vinyl acetate Polyvinyl chloride (2N3360, 2N3361, 2N3362)	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 do not raise different questions of safety and effectiveness.
Female Luer Lock	Copolyester (2N8374)	Polymethyl methacrylate (Acrylic) (2N3358, 2N3380, 2N3354, 2N3382, 2N3357, 2N3355, 2N3356, 2N3359, 2N3360, 2N3361, 2N3362, 2N3386)	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 do not raise different questions of safety and effectiveness.
Male Luer Lock	Acrylonitrile Butadiene Styrene (2N8374)	Same (2N3358, 2N3380, 2N3354, 2N3382, 2N3357, 2N3355, 2N3356, 2N3359, 2N3360, 2N3361, 2N3362, 2N3386)	N/A
Male Luer Cap	Polypropylene (2N8374)	High Density Polyethylene (Cap) Hydrophobic Filter, Acrylic (W/Non-Woven Nylon Substrate) (Filter Membrane) (2N3358, 2N3380, 2N3354, 2N3382, 2N3357, 2N3355, 2N3356, 2N3359, 2N3360, 2N3361, 2N3362, 2N3386)	The predicate device does not have the same type of material. 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.

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 5) were conducted to evaluate the functional performance of the proposed devices:

Table 5. Performance Data

Test	Acceptance Criteria
ISO 80369-7 Luer Tests on male Luer Lock Connector	BS EN ISO 80369-7:2016, Clause 6.1.2, BS EN ISO 80369-7:2016, Clause 6.1.3, ISO 80369-7:2016, Clause 6.2, ISO 80369-7:2016, Clause 6.3, ISO 80369-20:2015 AnnexE, ISO 80369-7:2016, Clause 6.1.2, ISO 80369-7:2016, Clause 6.1.3, ISO 80369-7:2016, Clause 6.4, ISO 80369-7:2016, Clause 6.5, ISO 80369-7:2016, Clause 6.6, ISO 80369-7: 2016, Clause 5, ISO 594-1:1986, Clause 3, ISO 594-2:1998, Clause 3 (as applicable)
ISO 80369-7 Luer Tests on female Luer Lock Connector	BS EN ISO 80369-7:2016, Clause 6.1.2, BS EN ISO 80369-7:2016, Clause 6.1.3, ISO 80369-7:2016, Clause 6.2, ISO 80369-7:2016 Clause 6.3, ISO 80369-20:2015 AnnexE, ISO 80369-7:2016, Clause 6.1.2, ISO 80369- 7:2016, Clause 6.1.3, ISO 80369-7:2016, Clause 6.4, ISO 803697:2016, Clause 6.5. ISO 80369-7:2016, Clause 6.6, ISO 80369-7:2016, Clause 5 (as applicable), ISO 594-1:1986, Clause 3, ISO 594-2:1998, Clause 3
Tensile Strength Test	BS EN ISO 8536-9, Clause 5.3, BS EN ISO 8536-10, Clause 4.3, BS EN ISO 8536-11, Clause 5.3, BS EN ISO 8536-12, Clause 6.2,
Leak Test	BS EN ISO 8536-9: 2015, Section A.4, BS EN ISO 8536-11:2015, Section A.4, ISO 8536-10: 2015, section A.4
Counter Flow Test	ISO 8536-12:2007+A1:2013, Clause A.4.

Table 5. Performance Data

Test	Acceptance Criteria
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
Notch Clamp Activation Force Test	Per Baxter Test Method
Notch Clamp Shut-Off Test	ISO 8536-14:2015
Filter Tests	EN ISO 8536-11, Clause 5.1 and per Baxter Test Method
Non-DEHP Claim Verification (< 0.1% DEHP)	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 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 were conducted on a worst case/representative final, finished device for all materials of the proposed devices. The following tests were conducted as part of the biocompatibility testing for the proposed devices' fluid path:

- Cytotoxicity ISO 10993-5
- Sensitization ISO 10993-10
- Intracutaneous (Irritation) Reactivity ISO 10993-10
- Systemic Toxicity (acute dose) ISO 10993-11
- Toxicological Assessment of Extractable Profile ISO 10993-17
- Materials Mediated Pyrogen ISO 10993-11
- Hemolysis ISO 10993-4
- Extractable Assessment ISO 10993-18

- 14 Day Systemic Repeat Dose Toxicity Study ISO 10993-11

Based upon the results of this prolonged duration, external communicating, indirect blood path testing, the proposed devices have been shown to be biocompatible and appropriate for their intended use.

Sterility:

The proposed devices are sterilized with gamma radiation. The products are in the bioburden (sub) category "General Sets Labeled 'Sterile" and "General Small Devices 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-steriilzation 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 potential points of microbial entry into the sterile fluid pathway of the proposed devices subject to this premarket notification. The Luer Connector Sites were tested following Baxter's test method. All test results meet their acceptance criteria and support that the proposed devices are appropriately designed for their intended use.

Particulate Matter Testing

Baxter has performed particulate matter testing per <USP 788> on the proposed devices subject to this premarket notification. All test results meet 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.