November 17, 2022

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

Re: K220558
Trade/Device Name: Blood Administration Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: BRZ
Dated: October 17, 2022
Received: October 21, 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 Joyce M. Whang, Ph.D.
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)*
K220558

Device Name

Blood Administration Sets

Indications for Use *(Describe)*

Applicable to Product Code 2N3383: For the administration of blood, blood components or solutions from a container into the patient's vascular system through a vascular access device.

Applicable to Product Code 2N3385: For the administration of blood, blood components or solutions from a container into the patient's vascular system through a vascular access device. Only for use with Neonates and Pediatrics. Not for use in Trauma situations.

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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Baxter

K220558 510(k) Summary

November 17, 2022

OWNER:

Baxter Healthcare Corporation
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Round Lake, IL 60073

CONTACT PERSON:

Meaghan Bonn
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IDENTIFICATION OF THE DEVICE:

Trade/Device Name: Blood Administration Sets
Classification Panel: 80 General Hospital
Regulation Number: 21 CFR 880.5440
Common Name: Blood Transfusion Set
Regulation Name: Intravascular Administration Sets
Regulatory Class: Class II
Product Code: BRZ

Table 1. Current Product Line

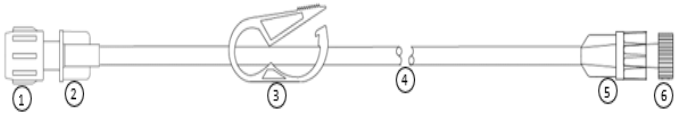
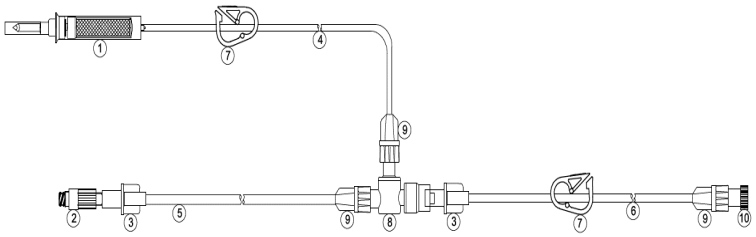
Code #	Device Description	
2N3383	Blood Extension Set, 59” (150 cm), Vol. 4.7 mL 	1: Non-Vented Cap for Female Luer Lock 2: Female Luer Lock 3: Notch Clamp 4: Tube 5: Male Luer Lock 6: Filter Vented Cap for Male Luer Lock

Table 2. Proposed Product Line

Code #	Device Description	
2N3383	Blood Extension Set, 59" (150 cm), Vol. 4.7 mL 	1: Non-Vented Cap for Female Luer Lock 2: Female Luer Lock 3: Notch Clamp 4: Tube 5: Male Luer Lock 6: Filter Vented Cap for Male Luer Lock
2N3385	Integrated Blood Set, 71" (180 cm), Vol 6.3 mL 	1: Blood Chamber 2: Clearlink LAV 3: Female Luer Lock 4, 5 & 6: Tube 7: Notch Clamp 8: Dual Anti-Syphon Valve 9: Male Luer Lock 10: Filter Vented Cap for Male Luer Lock

PREDICATE DEVICE:

Table 3. Predicate Device

Device	Company	Predicate 510(k)	Clearance Date
Blood Administration Sets	Baxter Healthcare Corporation	K210335 (Model 2N3383)	June 10, 2021

REASON FOR SUBMISSION:

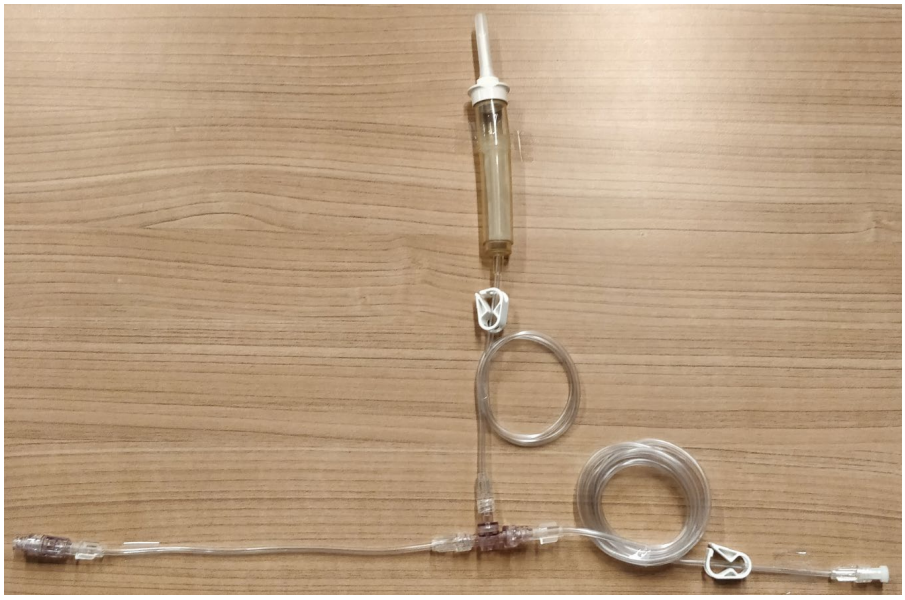
The basis for this premarket notification is the addition of another blood set configuration (Product Code 2N3385) to the current product line to provide an additional option to the clinician. The proposed device is a single use, non-pyrogenic, sterile, disposable device, intended for the administration of fluids from a container into the patient's vascular system through a vascular access device.

DESCRIPTION OF THE DEVICE:

Baxter's IV Administration Sets (Blood Administration Sets) are single use, non-pyrogenic, sterile disposable devices intended for the administration of fluids from a container into the patient's vascular system. They can be used to administer solutions, blood, and blood products to patients.

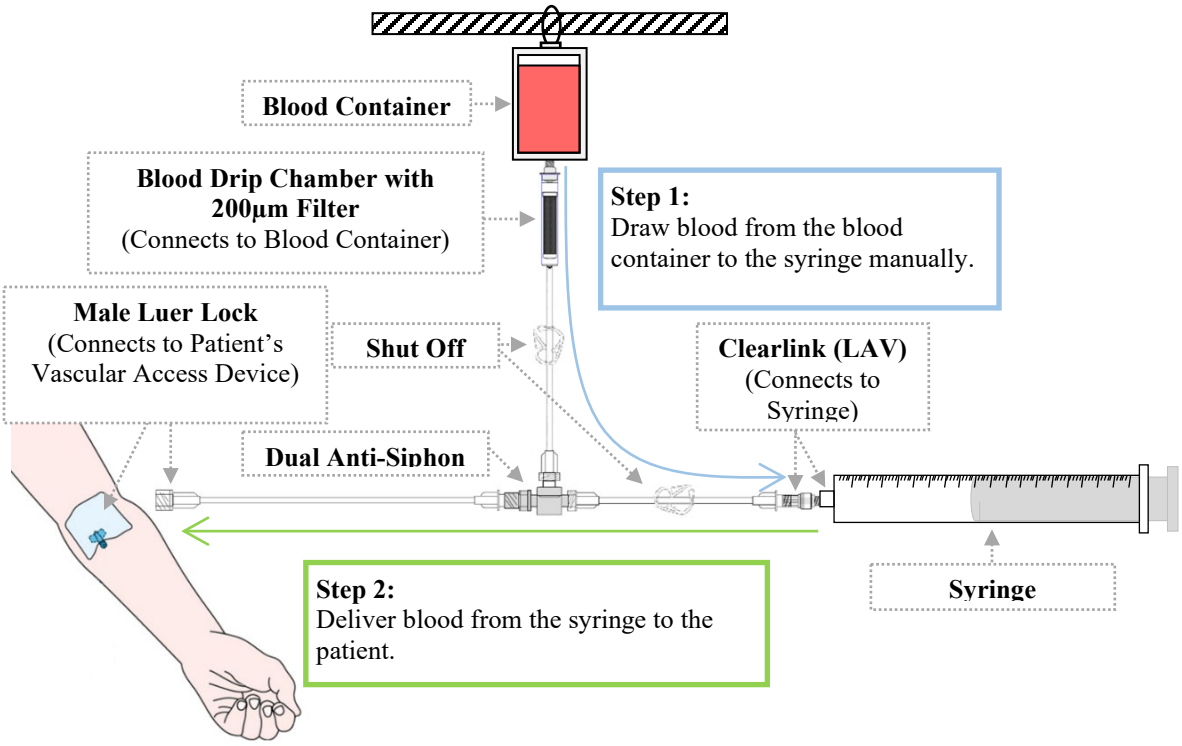
The proposed blood set configuration (Product Code 2N3385) consists of non-DEHP PVC (< 0.1% DEHP) tubing, blood chamber, 200 µm Filter, Clearlink Luer Activated Valve (LAV), notch clamp, female Luer lock, dual anti-syphon valve, male Luer lock, and a filter vented cap for a male Luer lock. It can be used to administer solutions, blood, and blood products to the patient. See Table 2 for the proposed device's configuration (Product Code 2N3385). See Figure 1 for a photograph of the proposed device.

Figure 1. Photograph of the proposed Blood Set (Code # 2N3385)



The blood set (2N3385) will be used for syringe-based infusion. The clinician attaches the blood set to a blood bag and manually draws blood into a syringe. The blood is then delivered into the patient's vascular system through a vascular access device. See **Figure 2** for the clinical set up for the proposed device. The total blood component volume administered via this set would be equivalent to the number of syringes filled from an aliquot of blood (i.e. typically a volume of 120-150 mL), therefore, clinical applications for the proposed device (2N3385) are limited to pediatric and neonatal patients requiring small volumes of blood.

Figure 2. Clinical Use Set Up of the proposed Blood Set (Code # 2N3385)



INDICATIONS FOR USE:

Applicable to Product Code 2N3383: For the administration of blood, blood components or solutions from a container into the patient's vascular system through a vascular access device.

Applicable to Product Code 2N3385: For the administration of blood, blood components or solutions from a container into the patient's vascular system through a vascular access device. Only for use with Neonates and Pediatrics. Not for use in Trauma situations.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed device is substantially equivalent to the predicate device, previously cleared under 510(k) premarket notification K210335 on June 10, 2021. The intended use and function of the proposed device is 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 K210335 (Product Code 2N3383)	Proposed Device (Product Code 2N3385)	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 blood, blood components or solutions from a container into the patient's vascular system through a vascular access device.	For the administration of blood, blood components or solutions from a container into the patient's vascular system through a vascular access device. **Only for use with Neonates and Pediatrics. Not for use in Trauma situations.**	The total blood component volume administered via the proposed device would be equivalent to the number of syringes filled from an aliquot of blood (i.e. typically a volume of 120-150 mL), therefore, clinical applications for the proposed device are limited to pediatric and neonatal patients requiring small volumes of blood. Trauma situations would require larger volumes of blood than the 120-150 mL in an aliquot of blood, therefore, the integrated blood set would not be clinically appropriate for a trauma situation.
Regulation Number	21 CFR 880.5440	Same	N/A
Product Code	BRZ	Same	N/A
Sterility	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	59" (150 cm)	71" (180 cm) (from the Clearlink LAV to the Filter Vented Cap for Male Luer Lock)	The proposed device is longer than the predicate device. Design control activities have been conducted and have confirmed, through design validation, that the length of the proposed device ensures a safe delivery without excessive manipulation of the set

Table 4. Device Comparison

Features	Predicate Device K210335 (Product Code 2N3383)	Proposed Device (Product Code 2N3385)	Assessment of Differences
			and patient discomfort. The longer length of the proposed device does not raise different questions of safety and effectiveness.
Tubing Inner / Outer Diameter	Inner Diameter: 2.0 mm Outer Diameter: 3.6 mm	Same	N/A
Priming Volume	4.7 mL	6.3 mL (from the Clearlink LAV to the Filter Vented Cap for Male Luer Lock)	The proposed device priming volume is nominally more 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			
Spike	N/A	Acrylonitrile Butadiene Styrene	The predicate device does not have this spike design. 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. Testing was performed per the standards and/or acceptance criteria listed in Table 5, line 12 through line 16.
Blood Chamber	N/A	Polyvinyl Chloride (Chamber) Polypropylene (Filter Housing) Polyamide (Nylon) (Filter Mesh)	The predicate device does not have this type of blood filter design. 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. Testing was performed per the standards and/or

Table 4. Device Comparison

Features	Predicate Device K210335 (Product Code 2N3383)	Proposed Device (Product Code 2N3385)	Assessment of Differences
			acceptance criteria listed in Table 5, line 9 through line 11.
Dual Anti-Siphon Valve	N/A	Polycarbonate (Housing) Silicone (Membrane)	The predicate device does not have a dual anti-syphon 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. Testing was performed per the standards and/or acceptance criteria listed in Table 5, line 6 through line 8.
Tubing	Polyvinyl Chloride	Same	N/A
Injection Site	N/A	Clearlink LAV Polycarbonate (Inlet/Outlet Housing) Silicone (Gland) Polycarbonate (Center Post)	The predicate device does not have a Clearlink LAV. 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. Testing was performed per the standards and/or acceptance criteria listed in Table 5, line 17.
Female Luer Lock	Polymethyl methacrylate (Acrylic)	Same	N/A
Male Luer Lock	Acrylonitrile Butadiene Styrene	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 5) were conducted to evaluate the functional performance of the proposed device:

Table 5. Performance Data

Line Item #	Test	Acceptance Criteria
1	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 80369-7:2016, Clause 6.4, ISO 80369-7:2016, Clause 6.5, ISO 80369-7:2016, Clause 6.6, ISO 80369-7:2016, Clause 5
2	Tensile Strength Test	ISO 1135-5:2015, Clause 6.3
3	Leak Test (Pressure Test)	ISO 1135-5:2015, Clause 6.2
4	Notch Clamp Activation Force Test	Activation force ≤ 50 N
5	Notch Clamp Shut-Off Test	No liquid or air leakage when subjected to 50 kPa for 15 sec
6	Counter Flow Test	ISO 8536-12:2007+A1:2013, Clause 6.5
7	Blocking Performance Test	ISO 8536-12:2007+A1:2013, Clause 6.7
8	Opening Pressure	Opening Pressure > 14.7 kPa
9	Blood Filter Tests (Uniform Pore Size Dimensional Compliance Test)	ISO 1135-5, Clause 6.6
10	Blood Filter Tests (Particle Retention Test)	ISO 1135-5, Clause 6.6
11	Chamber Squeezing Test	Force required to squeeze ≤ 91 N
12	ISO Spike Tests (Dimensional Compliance Test)	ISO 8536-4:2013+A1:2013, Section 6.4
13	ISO Spike Tests (Spike Secure Connection Test)	ISO 1135-5, Clause 6.4. No water leakage after spike to container connection of 5 hours
14	ISO Spike Tests (Spike Coring test)	ISO 1135-5, Clause 6.4
15	ISO Spike Tests (Spike to Blood Bag Traction Test)	ISO 1135-5, Clause 6.4.3

Table 5. Performance Data

Line Item #	Test	Acceptance Criteria
16	ISO Spike Tests (Spike to Blood Bag Leak Test)	ISO 1135-5, Clause 6.4.4
17	Clearlink LAV Tests (Clearlink LAV Leak Test – Post 100 Actuations)	No leakage when subjected to 200kPa for 15 sec after 100 actuations
18	Particulate Matter Test	USP <788>
19	Non-DEHP Claim Verification (< 0.1% DEHP m/m)	< 0.1% DEHP m/m
20	ISO 1135-5 Blood Component Compatibility Test	ISO 1135-5, Clause 8.6 and 8.7; ISO 1135-4, Clause 7.6 and 7.7
21	Shelf Life Microbial Ingress Testing of the Clearlink Luer Activated Valve (LAV) During Simulated Clinical Use	ANSI/AAMI CN27:2021; Annex E
22	Functional Performance Testing after Simulated Shipping/Transportation	No damaged product, including but not limited to, cracked or broken components, separated tip protectors, wall to wall kinked tubing.

All tests met the acceptance criteria.

Biocompatibility:

Biocompatibility assessments were conducted based on ISO-10993-1, Biological Evaluation of Medical Devices 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 final, finished devices to meet an ISO 10993-1 categorization of external communicating device, indirect blood path, prolonged contact duration. 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
- Acute Systemic Toxicity ISO 10993-11
- 30 Day Systemic Repeat Dose Toxicity Study ISO 10993-11

- Material Mediated Pyrogen ISO 10993-11
- Hemocompatibility ISO 10993-4

Based upon the results, the data supports an 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. 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 device 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 potential points of microbial entry into the sterile fluid pathway of the proposed device. The potential microbial entry points consist of the Clearlink Luer Activated Valve (LAV), the male Luer connector site, and the spike interface. Microbial ingress testing was conducted on the Clearlink LAV following section 8 of FDA's *Guidance for Industry and Staff, Intravascular Administration Sets Premarket Notification Submissions [510(k)], issued July 11, 2008*. The male Luer connector site was tested following Baxter's test method (as previously cleared under K180739) of challenging the connections during simulated clinical use to ensure the absence of microbial ingress to the sterile fluid path. The spike interface was tested following Baxter's test method (as previously cleared under K180739) of challenging the

interface 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 device is appropriately designed for its intended use.

CONCLUSION:

The differences between the predicate and the subject device do not raise any new or different questions of safety and 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.