May 28, 2019

Baxter Healthcare Corporation
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K180739
Trade/Device Name: Clearlink System Solution Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FPA
Dated: April 4, 2019
Received: April 5, 2019

Dear Mark Job:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Tina Kiang, Ph.D
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)*

K180739

Device Name
Clearlink System Solution Sets

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5. 510(k) Summary

May 24, 2019

OWNER:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

CONTACT PERSON:

Jeanette Licata
Sr. Regulatory Affairs Associate, Regulatory Affairs
32650 N. Wilson Road
Round Lake, IL 60073
Telephone: (224) 948 3996
Fax: (224) 270 4119

IDENTIFICATION OF THE DEVICE:

Trade/Device Name: Clearlink System Solution 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. Code Numbers for Clearlink System Solution Set

Code Number	Name
2R8519	Clearlink System Non-DEHP Continu-Flo Solution Set
2R8537	Clearlink System Non-DEHP Continu-Flo Solution Set
2R8546	Clearlink System Non-DEHP Continu-Flo Solution Set
2R8401	Clearlink System Non-DEHP Solution Set
2R8875	Clearlink System Solution Set with Duo-Vent Spike

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	October 18, 2011

REASON FOR SUBMISSION:

The changes identified as the basis of this submission apply to all the proposed devices included in this application (2R8519, 2R8537, 2R8546, 2R8401, and 2R8875). Specifically, the changes include the following:

- A change to the packaging configuration, specifically the design and materials of the male Luer cap and spike tip protector which are used to maintain the sterile fluid path. Both are non-fluid path components.
- Differences in components and materials

- Inclusion of the expiry date for the new packaging configuration
- Minor rewording of the Indications for Use and Intended Use statements
- An update to the pump compatibility statement
- Labeling updates with other clarifying information to comply with Baxter's labeling standards.

These modifications do not impact the intended use, fundamental scientific technology of the devices or raise different questions of safety and effectiveness.

Table 3 provides details on the design and materials of the current and proposed spike tip protector and male Luer cap.

DESCRIPTION OF THE DEVICE:

The Clearlink System Non-DEHP Solution Set (2R8401) consists of a spike tip protector, non-vented spike, non-DEHP drip chamber, non-DEHP tubing, slide clamp, regulating roller clamp, Clearlink Luer activated valve (LAV), two-piece male Luer lock and male Luer cap. The Clearlink System Solution Set with Duo-Vent Spike (2R8875) consists of a spike tip protector, vented spike, non-DEHP drip chamber , non-DEHP tubing, tri-layer tubing, slide clamp, on-off roller clamp, Clearlink Luer activated valve (LAV), one-piece male Luer lock and male Luer cap.

The Clearlink System Non-DEHP Continu-Flo Solution Set (2R8519, 2R8537, 2R8546) consists of a spike tip protector, non-vented spike, non-DEHP drip chamber , non-DEHP tubing, check valve, slide clamp, regulating roller clamp, Clearlink Luer activated valve (LAV), two-piece male Luer lock and male Luer cap. Configurations of these sets differ in drip chamber flow rate (60 drops/mL or 10 drops/ mL).

Table 3. Spike Tip Protector and Male Luer Cap, Current and Proposed

Component	Current Design; Material	Proposed Design; Material	Assessment of Differences
Spike Tip Protector	Vented; Low Density Polyethylene	Non-Vented; Linear Low Density Polyethylene	Spike tip protector and male Luer cap are removed before set use and are non-fluid path components. Additional testing has confirmed the different technological characteristics of the new device do not raise different questions of safety and effectiveness.
Male Luer Cap	Vented; Low Density Polyethylene, Blue	Non-Vented Filtered; High Density Polyethylene (housing), Acrylic with Non-Woven Nylon Substrate (filter material)	

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 (2R8519, 2R8537, 2R8546, 2R8401, 2R8875)	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.
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.

Table 4. Device Comparison

Features	Predicate Device Cleared under K112893	Proposed Devices (2R8519, 2R8537, 2R8546, 2R8401, 2R8875)	Assessment of Differences
			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
Pump Compatibility	Yes, compatible with Flo-Gard and Colleague	Yes, compatible with Sigma Spectrum and other Baxter infusion pumps	Compatible pumps reference has been updated to align with Baxter's marketed infusion pumps. Testing has been performed to confirm pump compatibility with Sigma Spectrum infusion pumps.
Components/Materials			
Non-Vented Spike (2R8519, 2R8537, 2R8546 and 2R8401)	Acrylonitrile Butadiene Styrene	Same	N/A
Non-DEHP Drip Chamber	Polyvinyl Chloride	Same	N/A
Non-DEHP Set Tubing (2R8537, 2R8546)	Material: Polyvinyl Chloride Plasticizer: Tris (2-Ethylhexyl) Trimellitate	Same	N/A
Clearlink Luer Activated Valve	Polycarbonate [Inlet/Outlet Housing] Silicone (Gland)	Same	N/A

Table 4. Device Comparison

Features	Predicate Device Cleared under K112893	Proposed Devices (2R8519, 2R8537, 2R8546, 2R8401, 2R8875)	Assessment of Differences
	Polycarbonate [Center Post]		
Two-Piece Male Luer Lock (2R8519, 2R8537, 2R8546 and 2R8401)	Acrylonitrile Butadiene Styrene	Same	N/A
Vented Spike (2R8875)	Acrylonitrile Butadiene Styrene	Same	N/A
Capped Vent Filter (Vented Spike) (2R8875)	Acrylic copolymer with nylon substrate (filter material) High density polyethylene (housing)	Same Same	N/A
Spike Tip Protector (2R8519, 2R8537, 2R8546, 2R8401 and 2R8875)	Low Density Polyethylene	Linear Low Density Polyethylene	The spike tip protector has passed functional testing for its intended use and is a non-fluid path component. Additional testing has confirmed maintenance of the sterile fluid path. The different technological characteristics of the new device do not raise different questions of safety and effectiveness.[a]
Male Luer Cap (2R8519, 2R8537, 2R8546, 2R8401 and 2R8875)	Low Density Polyethylene	Acrylic with non-woven Nylon Substrate (Filter material) High Density Polyethylene (Luer cap)	The filter and male Luer cap have passed functional testing for their intended uses and are non-fluid path. Additional testing has confirmed maintenance of the sterile fluid path. The different technological characteristics of the new device do not raise different questions of safety and effectiveness.[a]

Table 4. Device Comparison

Features	Predicate Device Cleared under K112893	Proposed Devices (2R8519, 2R8537, 2R8546, 2R8401, 2R8875)	Assessment of Differences
Non-DEHP Pump Tubing (2R8519, 2R8537, 2R8546, 2R8401 and 2R8875)	Material: Polyvinyl Chloride Plasticizer: Tris (2-Ethylhexyl) Trimellitate	Material: Polyvinyl Chloride Plasticizer: Di (2-Ethylhexyl) terephthalate	Both the predicate and proposed device contain PVC tubing. The proposed device's tubing uses a different plasticizer. Design control activities have been conducted and have confirmed that the different technological characteristics of the new device do not raise different questions of safety and effectiveness.
Non-DEHP Set Tubing (2R8519, 2R8537, 2R8646, 2R8401)	Material: Polyvinyl Chloride Plasticizer: Tris (2-Ethylhexyl) Trimellitate	Material: Polyvinyl Chloride Plasticizer: Di (2-Ethylhexyl) terephthalate	Both the predicate and proposed device contain PVC tubing. The proposed device's tubing uses a different plasticizer. Design control activities have been conducted and have confirmed that the different technological characteristics of the new device do not raise different questions of safety and effectiveness.
Set Tubing (2R8875)	Material: Polyvinyl Chloride Plasticizer: Tris (2-Ethylhexyl) Trimellitate	Tri-Layer: Linear low density polyethylene (inner layer) Polyolefin (middle layer) Polyvinyl Chloride (outer layer)	Both the predicate and proposed device contain tubing. The proposed device contains tri-layer tubing. Design control activities have been conducted and have confirmed that the different technological characteristics of the new device do not raise different questions of safety and effectiveness.
Check Valve (2R8519, 2R8537 and 2R8546)	Not Applicable	Polymethyl methacrylate (Acrylic) [Inlet and Outlet] Silicone Rubber [Disk]	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 new device do not raise different questions of safety and effectiveness.[b]

Table 4. Device Comparison

Features	Predicate Device Cleared under K112893	Proposed Devices (2R8519, 2R8537, 2R8546, 2R8401, 2R8875)	Assessment of Differences
Minidrip Adapter (2R8546)	Not Applicable	Rubber (Synthetic Polyisoprene) [Blue Plug] Stainless Steel [Cannula]	The predicate device does not have a minidrip adapter. Design control activities have been conducted and have confirmed that the different technological characteristics of the new device do not raise different questions of safety and effectiveness.[b]
Non-DEHP Bushing Tubing (2R8875)	Not Applicable	Material: Polyvinyl Chloride Plasticizer: Tris (2-Ethylhexyl) Trimellitate	The predicate device does not have Non-DEHP bushing tubing. Design control activities have been conducted and have confirmed that the different technological characteristics of the new device do not raise different questions of safety and effectiveness.
One-Piece Male Luer Lock (2R8875)	Acrylonitrile Butadiene Styrene	Acrylonitrile Butadiene Styrene	Both the predicate and proposed devices contain an ABS One-Piece male Luer lock. The proposed device's component has a slightly different design. Design control activities have been conducted and have confirmed that the different technological characteristics of the new device do not raise different questions of safety and effectiveness.

[a] Although this component is non-fluid path, it's used to maintain sterility of the fluid path and has been included as it is the basis of this premarket application.

[b] Due to the use of a singular predicate for this submission, the comparison table identifies that this is a new component from the predicate device. However, the proposed set configuration with this component was originally cleared in K961225. Additionally, this component has since been replaced with another version which has the same functional purpose, same/similar intended use and with the same type and duration of contact.

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 Clearlink System Solution Sets. We have included testing information supporting all of the specific changes which are the basis of submission but have also included all testing information in this application to provide a comprehensive package of testing information applicable to the proposed devices.

Table 5. Performance Data

Test	Acceptance Criteria
Male Luer Cap/Spike Tip Protector Removal Force Test	Per Baxter Test Method
Male Luer Cap/Spike Tip Protector Retention Test	Per Baxter Test Method
Continuous Bubble Test (Pump Compatibility)[a]	Per Baxter Test Method
Accumulated Bubble Test (Pump Compatibility) [a]	Per Baxter Test Method
Administration Set Integrity After Maximum Delivery (Pump Compatibility) [a]	Per Baxter Test Method
Upstream Occlusion (Pump Compatibility) [a]	Per Baxter Test Method
Downstream Occlusion (Pump Compatibility) [a]	Per Baxter Test Method
Flow Rate Accuracy (Pump Compatibility) [a]	Per Baxter Test Method
Solvent Bond Tensile Strength Test	Per Baxter Test Method
Solvent Bond Pressure Test	Per Baxter Test Method
Top End Tubing Assembly Clear Passage	Per Baxter Test Method
Spike Assembly Visual Inspection	Per Baxter Test Method
Drop Volume Accuracy, 10 drops/mL	Per Baxter Test Method
Drop Volume Accuracy, 60 drops/mL	Per Baxter Test Method
Cannula Pull Out Force	Per Baxter Test Method
Spike Assembly Insertion Force Test	Per Baxter Test Method
Spike Assembly Removal Force Test	Per Baxter Test Method
Slide Clamp Shut Off Test (Fixtured Slide Clamp)	Per Baxter Test Method
Slide Clamp Shut Off Test - Post 24 hours (Fixtured Slide Clamp)	Per Baxter Test Method

Table 5. Performance Data

Slide Clamp 7 Day Subsystem and Tubing Damage Test (Fixtured Slide Clamp)	Per Baxter Test Method
Slide Clamp Flow Stability Test (Fixtured Slide Clamp)	Per Baxter Test Method
Slide Clamp Tug Stability Test (Fixtured Slide Clamp)	Per Baxter Test Method
Slide Clamp Shut Off Test (plastic slide clamp)	Per Baxter Test Method
Slide Clamp 7 Day Subsystem and Tubing Damage Test (plastic slide clamp)	Per Baxter Test Method
Roller Clamp Control Range Test	Per Baxter Test Method
Roller Clamp Force Test	Per Baxter Test Method
Roller Clamp Shut Off Test -Post 24 hours	Per Baxter Test Method
Roller Clamp 7 Day Subsystem and Tubing Damage Test	Per Baxter Test Method
Roller Clamp Flow Stability Test	Per Baxter Test Method
Roller Clamp Tug Stability Test	Per Baxter Test Method
Roller Clamp Tubing Leak Test	Per Baxter Test Method
Roller Clamp Shut-Off Test	Per Baxter Test Method
Roller Clamp Force Test	Per Baxter Test Method
Check Valve Back Flow Test	Per Baxter Test Method
Check Valve High Pressure Test	Per Baxter Test Method
Clearlink Y-Site Valve Performance Post 100 Actuations	Per Baxter Test Method
Clearlink Y-Site Valve Performance Post 96 Hour Indwell	Per Baxter Test Method
Clearlink Y-Site Clear Air Passage	Per Baxter Test Method
Clearlink Y-Site Back Pressure Leak Test	Per Baxter Test Method
Clearlink Y-Site Luer Connection Leak Test	Per Baxter Test Method
Clearlink Y-Site Basic 10-Cycle Actuation Sequence	Per Baxter Test Method
ISO Luer Tests on Male Luer Connectors	ISO 594-1:1986 and 594-2:1998
ISO Luer Tests on Clearlink Connectors (Unscrewing Torque, Separation, Resistance to Overriding and Ease of Assembly Tests)	ISO 594-2:1998
Non-DEHP Claim Verification	Per Baxter Test Method

[a] All pump compatibility testing was performed with the Sigma Spectrum infusion pump.

All tests met the acceptance criteria.

Biocompatibility:

The spike tip protector and male Luer cap components are not considered part of the fluid path of the sets. The fluid path materials in these sets have been used in similar Baxter cleared devices with the same/similar intended use and with the same type and duration of contact.

For the device fluid path, biocompatibility assessments were conducted based on ISO-10993-1, Biological Evaluation of Medical Devices for prolonged duration, external communicating device, indirect blood path and Blue Book Memorandum G95-1 "*Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'*" as recommended in the IV 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 Clearlink System Solution Sets. The following tests were conducted as part of the biocompatibility testing for the device fluid path of the Clearlink System Solution Sets:

- Cytotoxicity ISO 10993-5
- Sensitization ISO 10993-10
- Intracutaneous (Irritation) Reactivity ISO 10993-10
- Systemic Toxicity (acute and repeat dose) ISO 10993-11
- Toxicological Assessment of Extractable Profile ISO 10993-17
- Materials Mediated Pyrogen ISO 10993-11
- Hemolysis ISO 10993-4
- USP Physiochemical USP <661> (Buffering capacity, Heavy metals, Non-Volatile Residue)

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

Sterility:

The Clearlink System Solution Sets are sterilized with radiation. 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 sterilization process for the proposed devices is also compliant to 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 2 (two) years.

Microbial Ingress Testing:

Baxter has conducted testing on all potential points of microbial entry into the sterile fluid pathway of the Clearlink Intravascular Administration sets subject to this premarket notification. Microbial ingress testing was conducted on the Clearlink Luer Activated Device (LAD) following section 8 of FDA's *Guidance for Industry and Staff, Intravascular Administration Sets Premarket Notification Submissions [510(k)]*, issued July, 11, 2008. The Spike Area and the Luer Connector Site were tested following Baxter's test method. All test results meet their acceptance criteria and support that the proposed devices are appropropriately 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.