DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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July 19, 2017

CareFusion, Inc.
% Mark Job
Regulatory Technology Services, LLC
1394 25th Street North West
Buffalo, Minnesota 55313 11021

Re: K171957
Trade/Device Name: MaxZero™ Extension Sets with Needleless Connector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: June 28, 2017
Received: June 29, 2017

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tara A. Ryan -S

for

Lori Wiggins
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
MaxZero™ Extension Set with Needle-Free Connector(s)

Indications for Use *(Describe)*

Pressure Rated: The MaxZero™ Extension Set with Needle-Free Connector(s) is for single use only. The MaxZero™ Extension Set with Needle-Free Connector(s) may be used for direct injection, intermittent infusion, continuous infusion or aspiration. This set may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10mL per second.

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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510(k) K171957 Summary

Submitter Information

Submitter: CareFusion, Inc.

10020 Pacific Mesa Blvd.
San Diego, CA 92121, USA
Contact Person: Viviana Lai
Phone: 714-922-7679
Email: Viviana.lai@carefusion.com
Date Prepared: June 23, 2017

Subject Device Identification

Trade Name: MaxZero™ Extension Set with Needle-Free Connector(s)
Common Name: Intravascular Administration Set
Classification Name: Intravascular Administration Set
Classification Panel: General Hospital
Regulation Number: 21 CFR 880.5440
Regulatory Class: Class II
Product Code: FPA

Predicate Device Identification

Trade Name: MaxZero™ Extension Sets with Needleless Connector
Manufacturer: Carefusion, Inc.
510k Number: K140831
510K Clearance Date: April 15 2014

Reason for Submission

The objective of this submission is to introduce new components such as Needless Access Connector–Y (NAC-Y also known as Y-site) and Needless Access Connector-T (NAC-T also known as T-connector) connectors to the MaxZero™ Extension Set with Needle-Free Connector(s) product line configurations.

Device Description

The MaxZero™ Extension Set with Needle-Free Connector(s) are intravascular extension sets intended for single patient use, including pediatrics (neonates, infants, children, adolescents) and immunocompromised patients, for direct injection, intermittent infusion continuous infusion or aspiration of drugs, blood and fluids. All MaxZero™ Extension Set with Needle-Free Connector(s) include the previously cleared zero reflux MZ1000 needleless Connector bonded to the extension set tubing. The MZ1000 needleless connector allows thorough and easy disinfection due to a solid, flat smooth surface and eliminates the risk of needle stick injuries. The MaxZero™ needleless connectors are sterile single patient devices that can be used for seven (7) days and 200 activations. All extension sets included in this submission are not made from natural rubber latex or DEHP.

Indication for Use

Pressure Rated: The MaxZero™ Extension Set with Needle-Free Connector(s) is for single use only. The MaxZero™ Extension Set with Needle-Free Connector(s) may be used for direct injection, intermittent infusion, continuous infusion or aspiration. This set may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10mL per second.

Technological Characteristics

The information provided in the premarket notification demonstrates that the subject device, MaxZero™ Extension Set with Needle-Free Connector(s), is substantially equivalent to the legally marketed predicated devices. The subject device and the predicate device are intended to be used for the delivery and/or aspiration of fluids to/from an IV catheter in a hospital environment. The subject and the predicate devices are similar in physical properties, materials, and configuration. Each device includes connectors that allow for needleless access to the IV line during IV therapy eliminating the risk of needle injury. The subject device incorporates MaxZero™ Needleless Connector attached to IV tubing. Components of the subject devices are made of materials that are substantially equivalent to the predicate devices listed above and this submission includes comprehensive biocompatibility testing for all device materials included in this submission.

Substantial Equivalence Table

	MaxZero™ Extension Set with Needle-Free Connector(s) (Subject Device)	**CareFusion MaxZero™ Extension Sets with Needleless Connector (Predicate device- K140831)**
FDA Reg. Number	21 CFR 880.5440	21 CFR 880.5440
FDA Regulation Name	Intravascular Administration Set	Intravascular Administration Set
FDA Class	Class II	Class II
FDA Product Code	FPA	FPA
Product Description	MaxZero™ Extension Set with Needle-Free Connector(s) and the predicate devices are sterile, single patient use, including pediatrics (neonates, infants, children, adolescents) and immunocompromised patients for direct inject, intermittent infusion, continuous infusion or aspiration of drugs, blood and fluids	MaxZero™ Extension Sets with Needleless Connector and the predicate devices are sterile, single patient use, including pediatrics and immunocompromised patients for direct inject, intermittent infusion, continuous infusion or aspiration of drugs, blood and fluids
Intended Use	The MaxZero™ Extension Set with Needle-Free Connector(s) is a sterile single patient use device intended to be used for the delivery and/or aspiration of fluids to/from an IV catheter.	The MaxZero™ Extension Sets With Needleless Connector is a sterile single patient use device intended to be used for the delivery and/or aspiration of fluids to/from an IV catheter.
Indications for Use	Pressure Rated: The MaxZero™ Extension Set with Needle-Free Connector(s) is for single use only. The MaxZero™ Extension Set with Needle-Free Connector(s) may be used for direct injection, intermittent infusion, continuous infusion or aspiration. This set may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10mL per second.	Pressure Rated: The MaxZero™ multi fuse extension set with needleless connector(s) is for single use only. The extension set may be used for direct injection, intermittent infusion, continuous infusion or aspiration. This set may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10mL per second. Non Pressure Rated: The MaxZero™ multi fuse extension set with needleless connector(s) is for single use only. The extension set may be used for direct injection, intermittent infusion, continuous infusion or aspiration.
Needless Connector	CareFusion MZ1000	CareFusion MZ1000

	MaxZero™ Extension Set with Needle-Free Connector(s) (Subject Device)	**CareFusion MaxZero™ Extension Sets with Needleless Connector (Predicate device- K140831)**
Device Components	MZ1000 Needleless Connector, PVC tubing with various lengths, slide clamps, male luer (spin lock), female luer (female wing adapter), NAC- Y connectors (Y-sites), NAC-T connectors (T-connectors)	MZ1000 Needleless Connector, PVC tubing with various length and ID/OD, check valves, anti-siphon valves, slide clamps, Y connectors, T-connectors, stopcocks, male spin lock and female wing adapter
Provided Sterile	Yes	Yes
Single Use	Yes	Yes

Explanation of Similarities and Differences technological Characteristics compared to Predicate Device

The Subject MaxZero™ Extension Set with Needle-Free Connector(s) have the following similarities to the predicate devices:

- Same Intended Use and Indication for Use
- Principle of operation
- Device Design
- Zero Reflux Needleless Connector
- Designed to prevent microbial ingress
- Needleless connector can be disinfected with 3 sec scrub with 70% IPA
- Maximum clinical use of 7 days 200 activations for the needleless connector (single patient use)
- Non-hemolytic and Non-pyrogenic
- Can be used with low power injectors with maximum of 325 psi & flow rate of 10ml/second (pressure rated sets)
- Not made with DEHP and not made with natural latex rubber
- Safe for use in MRI environment
- Sets can be used with harsh infusates

The following are technical characteristics differences between the subject and predicate devices:

- The subject device includes Needleless Access Connector-Y (NAC-Y also known as Y site) and Needless Access Connector-T (NAC-T also known as T connector) connectors that provide additional access ports.

Discussion of Performance Data:

Non-Clinical Data

CareFusion performed design verification performance testing to verify, demonstrate and support the claim of substantial equivalence to the predicate devices. All test results met their acceptance criteria and support that the MaxZero™ Extension Set with Needle-Free Connector(s) are appropriately designed for their intended use.

Carefusion performed design verification performance testing according to the FDA recognized performance standards and guidelines.

- ISO 594-1:1986 Conical fittings with a 6% (luer) taper of syringes, needles and certain other medical equipment – Part 1: General requirements"
- ISO 594-2:1998 Conical fittings with 6%(luer) taper for syringes, needles, and certain other medical equipment – Part 2 Locking fittings"
- ISO 8536-4:2010 "Infusion equipment for medical use- Part 4: Infusion set for single use, gravity feed"
- ISO 8536-8:2004 "Infusion equipment for medical use – Part 8: Infusion equipment for medical use. Infusion equipment for use with pressure infusion apparatus"
- ISO 8536-9:2004 "Infusion equipment for medical use – Part 9: Fluid lines for single use with pressure infusion equipment"
- ISO 8536-10:2004 "Infusion equipment for medical use – Part 10: Accessories for fluid lines for single use with pressure infusion equipment"
- ISO 14971:2007 "Medical devices- Application of risk management to medical devices"
- Guidance for Industry and FDA Staff - Intravascular Administration Sets Premarket Notification Submission[510(k)], July 11,2008

The following additional performance data were collected.

- Microbial Ingress and Barrier testing
- High-Pressure Testing
- Air Water Interface Visibility
- Set Internal Excess Pressure Testing
- Clamps – Internal Excess Pressure and Tubing Open Fluid Path Testing
- Bond Pull Testing
- Priming Volume and Flow Rate Testing
- Harsh Infusates Testing

Biocompatibility

Biocompatibility assessments were conducted in accordance with ISO-10993-1:2009, "Biological evaluation of medical devices – part 1: Evaluation and testing within a risk management process," Carefusion performed the biocompatibility testing of the components and finish product according to the following parts of the ISO 10993 standard.

- ISO 10993-2:2006: "Biological evaluation of medical devices – part 2: Animal welfare requirements"
- ISO 10993-4:2002: "Biological evaluation of medical devices – part 4: Selection of tests for interactions with blood"
- ISO 10993-5:2009: "Biological evaluation of medical devices – part 5: Tests for in vitro cytotoxicity"
- ISO 10993-10:2010: "Biological evaluation of medical devices – part 10: Tests for irritation and delayed-type hypersensitivity"
- ISO 10993-11:2006: "Biological evaluation of medical devices – part 11: Test for systemic Toxicity"
- ISO 10993-12:2012: "Biological evaluation of medical devices – part 12: Sample preparation and reference materials"

Sterilization and Shelf life

The subject device, MaxZero™ Extension Set with Needle-Free Connector(s), is radiation sterilized and the shelf life data supports a shelf life claim of 3 years. Sterilization and shelf life testing were completed according to the following FDA recognized guidelines:

- ISO 11137-1:2006 "Sterilization of health care products - Radiation- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices"
- ISO 11137-2:2006 "Sterilization of health care products - Radiation Part 2 – Establishing the sterilization dose"
- ISO 11607:2003 "Packaging for terminally sterilized medical devices"
- ASTM F1980-07: 2002 "Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices"
- ASTM F1140:2000 "Standard Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization within Restraining Plates"
- ASTM D4169: 1998 " Standard Practice for Performance Testing of Shipping Containers and Systems"
- ASTM-F1929-98(04): 1998 "Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration"

Clinical Data

There is no clinical data included in this submission.

Conclusion

The device met the acceptance criteria for all functional, microbial ingress, sterility, biocompatibility and other performance criteria. The conclusions drawn from the nonclinical tests that demonstrate that the new device is as safe, as effective, and performs as well as the predicate device.