October 23, 2020

Carefusion, Inc.
Nesli Karakaya
Sr. Manager, Regulatory Affairs
120 S State College Blvd, Suite 100
Brea, California 92821

Re: K193088
Trade/Device Name: MaxZero™ Extension Sets with Needle-Free Connector(s)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: September 22, 2020
Received: September 23, 2020

Dear Nesli Karakaya:

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)*
K193088

Device Name

MaxZero™ Extension Sets with Needle-Free Connector(s)

Indications for Use *(Describe)*

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 of drugs, blood and fluids.

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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K193088 **510(k) Summary**

Submitter Information

Submitter:	CareFusion, Inc.
	120 S State College Blvd Brea, CA 92821, USA
Contact Person:	Nesli Karakaya
Phone:	+41 21 556 3192
Email:	Nesli.Karakaya@bd.com
Date Prepared:	October 20, 2020

Subject Device Identification

Trade Name:	MaxZero™ Extension Sets 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
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
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 amber tubing that is resistant to UV light, trifurcated adaptors that connects 3 legs of tubing to a single male luer and filters that help prevent particles from flowing through the IV fluid line to the MaxZero™ Extension Sets with Needleless Connector(s).

Device Description

The MaxZero™ Extension Sets with Needle-Free Connector(s) are intravascular extension sets intended for single patient use, including pediatrics and immunocompromised patients, for direct injection, intermittent infusion continuous infusion or aspiration of drugs, blood and fluids. The MaxZero™ Extension Sets with Needle-Free Connector(s) are sterile single patient devices that can be used for up to seven (7) days and 200 activations. All extension sets included in this submission are not made from natural rubber latex or DEHP.

The following table lists the components that the device is comprised of.

Components	Description
MaxZero Needle-free Connector	Needle-free connector used for the delivery or aspiration of drugs, blood and fluids to/from an IV catheter
Amber tubing	Delivers fluid to/from patient while blocking UV light
Filters	Filters out particulate
Slide Clamp	To close fluid path along tubing
Male Luer (spin lock)	Connects distal end of set to female luer
Bifurcated connectors (Y-connectors)	Merges two legs of tubing into single leg
Trifurcated adapter	Connects 3 legs of tubing to a single male luer

Indication for Use

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 of drugs, blood and fluids.

Technological Characteristics

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

Proposed MaxZero Extension Sets

Model Number	Description	Tubing	ID	OD
MZ9303	Microbore amber extension set, IV connector (70")	Microbore Amber	0.023"	0.079"
MZ9321	Microbore amber extension set, IV connector, 0.2 micron filter (81")	Microbore Amber	0.023"	0.079"
MZ9299	Microbore quad-fuse extension set, 4 IV connectors, 1 amber tubing lead, 3 clear tubing leads (7")	Microbore Amber	0.023"	0.079"
		Microbore Clear	0.020"	0.079"
MZ9328	Minibore amber extension set, IV connector, 1.2 micron filter (81")	Minibore Amber	0.042"	0.079"

Substantial Equivalence Table

	MaxZero™ Extension Sets with Needle-free Connector(s) (Subject Device)	CareFusion MaxZero™ Extension Sets with Needleless Connector (K140831)	Equivalence
FDA Reg. Number	21 CFR 880.5440	21 CFR 880.5440	Same
FDA Regulation Name	Intravascular Administration Set	Intravascular Administration Set	Same
FDA Class	Class II	Class II	Same
FDA Product Code	FPA	FPA	Same
Product Description	MaxZero™ Extension Sets with Needle-free Connector(s) 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	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	Same
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 or aspiration	The MaxZero™ Extension Sets with Needleless Connector is a sterile single patient use device intended to be used for the delivery	Equivalent Clarified delivery or aspiration of drugs, bloods and fluids. This is equivalent to

	MaxZero™ Extension Sets with Needle-free Connector(s) (Subject Device)	CareFusion MaxZero™ Extension Sets with Needleless Connector (K140831)	Equivalence
	of drugs, blood and fluids to/from an IV catheter.	or aspiration of fluids to/from an IV catheter.	the device description of the predicate device.
Indication for use	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 of drugs, blood and fluids.	**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.	Equivalent to non-pressure rated sets The subject device is not indicated for power injection. All subject devices are non-pressure rated sets. Clarified delivery and/or aspiration of drugs, bloods and fluids. This is equivalent to the device description of the predicate device.
Device Length	• MZ9303 Microbore amber extension set, IV connector (70" Total Length) • MZ9321 Microbore amber extension set, IV connector, filter (81" Total Length) • MZ9299 Microbore quad-fuse extension set, 4 IV connectors, 1 amber tubing lead (7" Total Length)	• MZ5301 Pressure rated extension set, MaxZero connector, slide clamp, spin male luer lock (7" Total Length) • MZ5301 Pressure rated extension set, MaxZero connector, slide clamp, spin male luer lock (7" Total Length) • MZ5304 Pressure rated extension set, MaxZero connector, slide clamp, spin male	Different New lengths added - subject device has the same intended use as the predicate device. Length differences were tested according to applicable consensus standards (same as the predicate device).

	MaxZero™ Extension Sets with Needle-free Connector(s) (Subject Device)	CareFusion MaxZero™ Extension Sets with Needleless Connector (K140831)	Equivalence
	• MZ9328 Minibore amber extension set, IV connector, filter (81" Total Length)	luer lock (7" Total Length) • MZ5305 Pressure rated extension set, MaxZero connector, spin make luer lock (7" Total Length) • MZ5306 Pressure rated extension set, minibore tubing, MaxZero connector, spin make luer lock (7" Total Length) • MZ5307 Bi-fuse pressure rated extension set, minibore tubing, (2) MaxZero connectors, (2) side clamps, spin male luer lock. (7" Total Length) • MZ3508 Bi-fuse pressure rated extension set, minibore tubing, (2) MaxZero connectors, (2) slide clamps, spin make luer lock. (6" Total Length) • MZ9284 Bi-fuse pressure rated extension set, minibore tubing, (2) MaxZero connectors, (2) check valves (2) slide clamps, spin make luer lock (7" Total Length) • MZ9285 Bi-fuse pressure rated extension set, minibore tubing, (2) MaxZero connectors,	

	MaxZero™ Extension Sets with Needle-free Connector(s) (Subject Device)	**CareFusion MaxZero™ Extension Sets with Needleless Connector (K140831)**	**Equivalence**
		(2) check valves (2) slide clamps, spin make luer lock (7" Total Length)	
Fluid Contacting Material Composition	**Needle-free Connector:** Polycarbonate, silicone rubber **Tubing:** Non DEHP PVC **Bi-F Connector:** Rigid PVC **Tri-F Connector:** Acrylic **Male Luer (Spinlock):** ABS **Amber Tubing:** Non DEHP PVC **Filters:** Acrylic, Filter Media	**Needle-free Connector**: Polycarbonate, silicone rubber **Tubing:** Non DEHP PVC **Bi-F Connector**: Rigid PVC **Back Check Valve:** ABS, silicon rubber **Male Luer Adapter**: ABS **Male Spinlock:** ABS **Female Luer:** Copolyester	Different New Materials included in subject device: Acrylic, Filter Media. Design Control activities have been conducted and have confirmed the different technological characteristics of the proposed device do not raise different questions of safety and effectiveness
Configurations	MaxZero Needle-free Connector, PVC tubing with various length and ID/OD, clear tubing, amber tubing, in-line filters of various sizes, slide clamps, male luer (spin lock), female luer (female wing adapter), bifurcated connectors (Y-connectors) and trifurcated adapter	MaxZero Needleless Connector, tubing of various length and ID/OD, back check valve, slide clamps, pinch clamps, Y connectors, male spin lock and female wing adapter depending on configuration	Different New Components included in subject device: Amber tubing, filters, trifurcated adaptor. Design Control activities have been conducted and have confirmed the different technological characteristics of the proposed device do not raise different questions of safety and effectiveness
Physical Specification	Up to quad-fuse extension set. Lengths from 6" to 81"	Up to 2-piece extension set. Average length 7"	Different Design Control activities have been conducted and have confirmed the different technological characteristics of the

	MaxZero™ Extension Sets with Needle-free Connector(s) (Subject Device)	**CareFusion MaxZero™ Extension Sets with Needleless Connector (K140831)**	**Equivalence**
			proposed device do not raise different questions of safety and effectiveness
Filter Size	0.2 Micron Filter 1.2 Micron Filter	NA	Different Design Control activities have been conducted and have confirmed the different technological characteristics of the proposed device do not raise different questions of safety and effectiveness
Tubing Bore	Micro Bore = .023 ID X .079 OD Mini Bore = .042 ID X .079 OD	Standard Bore =.060 ID X 0.144 OD Micro Bore = .023 ID X .079 OD	Different New tubing added: Mini bore tubing Design Control activities have been conducted and have confirmed the different technological characteristics of the proposed device do not raise different questions of safety and effectiveness
NON-DEHP tubing	Yes	Yes	Same
Bonding agent	Cyclohexanone, Methylene Chloride, and Methyl Ethyl Ketone	Cyclohexanone	Different Bonding Agents used Design Control activities have been conducted and have confirmed the different technological characteristics of the proposed device do not raise different

	MaxZero™ Extension Sets with Needle-free Connector(s) (Subject Device)	**CareFusion MaxZero™ Extension Sets with Needleless Connector (K140831)**	**Equivalence**
			questions of safety and effectiveness
No natural rubber latex	Yes	Yes	Same
Sterilization Method	E-Beam	E-Beam	Same
Biocompatibility	ISO 10993-1	ISO 10993-1	Same
Non-Pyrogenic	Yes	Yes	Same
Usable Life	Up to 7 days 200 activation	7 days 200 activation	Equivalent Clarification added for up to 7 days
Disinfect with 70% Isopropyl Alcohol	Disinfect with 70% Isopropyl Alcohol	Disinfect with 70% Isopropyl Alcohol	Same
Performance			
Priming Volume	0.7mL – 2.0mL	Avg. 0.66 mL – 0.99 mL	Different Design Control activities have been conducted and have confirmed the different technological characteristics of the proposed device do not raise different questions of safety and effectiveness
Vacuum Integrity	-2.9 psi vacuum	-3.0 psi vacuum	Different Design Control activities have been conducted and have confirmed the different technological characteristics of the proposed device do not raise different questions of safety and effectiveness
Maximum Pressure	30 psi non-pressure rated sets	45 psi non-pressure rated sets	Different Subject device requirement has been aligned with

	MaxZero™ Extension Sets with Needle-free Connector(s) (Subject Device)	**CareFusion MaxZero™ Extension Sets with Needleless Connector (K140831)**	**Equivalence**
			ISO 8536 which specifies 30 psi (200 kPa)
Shelf Life	1 Year	3 Years	Equivalent
Tubing Transparency (Clear Tubing)	Pass	Pass	Same
Light Resistance (Amber Tubing)	Blocks a minimum of 90% of UV light at any wavelength between 250-450 nm	N/A	Different New component added: Amber tubing Design Control activities have been conducted and have confirmed the different technological characteristics of the proposed device do not raise different questions of safety and effectiveness

Explanation of Similarities and Differences technological Characteristics compared to Predicate Device

The Subject MaxZero™ Extension Sets 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
- Needle-free connector can be disinfected with 3 sec scrub with 70% IPA
- Maximum clinical use of up to 7 days 200 activations for the needleless connector (single patient use)
- Non-hemolytic and Non-pyrogenic
- Not made with DEHP and not made with natural latex rubber
- Sets tested to be used with harsh infusates

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

- The subject device includes amber tubing that is resistant to UV light

- The subject device includes filters that help prevent particles from flowing through the IV fluid line
- The subject device has new materials
- The subject device includes trifurcated adaptor that provides multi-fuse set with both amber and clear tubing
- The subject device includes mini bore tubing and different bonding agent
- The subject device includes different in priming volume, Vacuum Integrity, Maximum pressure and Shelf life
- The subject device offers new lengths

Design Control activities have been conducted and have confirmed the different technological characteristics of the proposed device do not raise different questions of safety and effectiveness.

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 Sets with Needle-free Connector are appropriately designed for their intended use.

Carefusion performed design verification performance testing according to the FDA recognized/voluntary consensus 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 8536-8:2015 "Infusion equipment for medical use – Part 8: Infusion equipment for medical use. Infusion equipment for use with pressure infusion apparatus"
- ISO 8536-9:2015 "Infusion equipment for medical use – Part 9: Fluid lines for single use with pressure infusion equipment"
- ISO 8536-10:2015 "Infusion equipment for medical use – Part 10: Accessories for Fluid lines for single use with pressure infusion equipment"
- ISO 8536-11:2015 "Infusion equipment for medical use – Part 11 Infusion filters for use with pressure infusion equipment"
- ISO 14971:2016 "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
- USP <788> "Particulate Matter in Injections"

The following tests were conducted according to the above standards:

- Leakage
- Separation Force
- Unscrewing Torque
- Ease of Assembly
- Resistance to Overriding
- Stress Cracking
- Particulate Contamination
- Tensile Strength
- Tubing: air/water interface only, not applicable to sets with light blocking tubing
- Fluid Filter
- Male Conical Fitting
- Protective Caps
- Chemical Requirements
- Biological Requirements

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 MaxZero™ Extension Sets with Needle-Free Connector(s) device is radiation sterilized and the shelf life data supports a shelf life claim of 1 year. Sterilization and shelf life testing were completed according to the following FDA recognized standards:

- 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 11607-1:2006 “Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems, and packaging systems”
- 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”

In addition to the above testing performed according to the ISO standards, the following performance testing was also conducted:

- UV Light Resistant: Test for light resistant ability of tube
- Flow Testing: Testing for flow of microbore and minibore tubing
- Clamps: Internal Excess Pressure and Tubing Open Fluid Path Testing
- Peak Pressure testing: Internal fluid peak pressure testing
- Priming volume testing: Priming volume is measured to have an approximate average of priming volume.
- Harsh Infusates testing: Device tests for multiple days with worst case infusates
- Air Water Interface Visibility (Clear Tubing)
- Microbial Ingress

Clinical Data

There are no clinical data included in this submission.

Conclusion

The subject MaxZero™ Extension Sets with Needle-Free Connector(s) met all predetermined acceptance criteria for functional, microbial ingress, sterility, biocompatibility, and other performance testing. Results of this testing demonstrate that the subject device is substantially equivalent to the predicate device.