DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
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August 15, 2017

Cair L.G.L.
Delphine Molinari
Official Correspondent
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69380 Lissieu
FRANCE

Re: K171118
Trade/Device Name: Carefusion Neutraclear™ multi-fuse Extension Set with Needle-free Connector(s)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: June 21, 2017
Received: July 10, 2017

Dear Delphine Molinari:

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" (21CFR 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 Wiggin, CPT
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Change Control Table, Change History

Change Control Table

Version	Document Author	Document Approver	Date Approved
1.00	Name, Title, Office	Name, Title, Office	MM/DD/YYYY

Complete Change Control Table (all versions) retained in SWIFT Docs.

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)*
K171118

Device Name
Carefusion NeutraClear™ multi-fuse Extension Set with needle-free connector(s)

Indications for Use *(Describe)*
Non- pressure rated: The Carefusion NeutraClear™ multi-fuse Extension Set with needle-free connector(s) is for single use only. The extension set can be used for direct injection, intermittent infusion, continuous infusion, or aspiration.

Pressure rated: The Carefusion NeutraClear™ multi-fuse Extension Set with needle-free connector(s) is for single use only. The extension set can 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 325psi at a flow rate of 10mL/s.

Type of Use *(Select one or both, as applicable)*

[X] 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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K171118

I. Submitter's Identification

Submitter Name: Cair L.G.L
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E-mail: dmolinari@cairlgl.fr
Date of Preparation: August 3rd 2017

II. Identification of the device

Subject Device

Trade Name: Carefusion NeutraClear™ multi-fuse Extension Set with needle-free connector(s)
Common Name: IV Extension Set
Classification Name: Intravascular administration set
Product Code: FPA
Regulation: 21 CFR 880.5440
Device Class: II
510k Number : K171118

Predicate Device

Trade Name: MaxZero Extension Set with Needleless connector
Common Name: IV Extension Set
Classification Name: Intravascular administration set
Product Code: FPA
Regulation: 21 CFR 880.5440
Device Class: II
510k Number: K140831

III. Device Description

Carefusion NeutraClear™ multi-fuse Extension Set with needle-free connector(s) are Extension Sets that are intended for single patient use, including pediatrics and immunocompromised patients, for direct injection, intermittent infusion, continuous infusion or aspiration of drugs, blood or fluids. All Carefusion NeutraClear™ multi-fuse Extension Set with needle-free connector(s) has a Neutraclear connector that is removable or bonded to the extension set tubing. Carefusion NeutraClear™ multi-fuse Extension Set with needle-free connector(s) allows thorough and easy disinfection due to a solid flat smooth surface and eliminates the risk of needle stick injuries. Carefusion NeutraClear™ multi-fuse Extension Set with needle-free connector(s) are sterile single patient devices that can be used for 200 activations and for 7 days. All extension set included are not made from natural rubber latex or DEHP.

IV. Indication for Use

Non- pressure rated: The Carefusion NeutraClear™ multi-fuse Extension Set with needle-free connector(s) is for single use only. The extension set can be used for direct injection, intermittent infusion, continuous infusion, or aspiration.

Pressure rated: The Carefusion NeutraClear™ multi-fuse Extension Set with needle-free connector(s) is for single use only. The extension set can 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 325psi at a flow rate of 10mL/s.

V. Technological Characteristics

Similarities between the predicate device and the subject device:

The subject device will have the same indication for use, principles of operation, same duration of use and the same resistance to pressure injectors (325psi with a flow rate of 10ml per second) as the predicate device.

Difference between the predicate device and the subject device:

The subject device will have a different sterilization method as the predicate device (but the sterilization method has been verified and validated by testing to demonstrate the subject device is sufficient for its intended use and therefore substantially equivalent to the predicate device).

For more details, please see below for a comparison table of the Carefusion NeutraClear™ multi-fuse Extension Set with needle-free connector(s) and the predicate device.

Substantial Equivalence Table

	Carefusion NeutraClear™ multi-fuse Extension Set with needle-free connector(s), (Subject Device)	MaxZero Extension Set with Needleless Connector	Substantial Equivalence
FDA Reg. Number	21 CFR 880.5440	21 CFR 880.5440	Equivalent
FDA Regulation Name	Intravascular Administration Set	Intravascular Administration Set	Equivalent
FDA Class	Class II	Class II	Equivalent
FDA Product Code	FPA	FPA	Equivalent
Product Description	Carefusion NeutraClear™ multi-fuse Extension Set with needle-free connector 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 Set 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	Equivalent
Intended Use	Carefusion NeutraClear™ multi-fuse Extension Set with needle-free 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.	The MaxZero Extension Set 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.	Equivalent
Indications for Use	Non Pressure Rated: The Carefusion NeutraClear™ multi-fuse Extension Set with needle-free connector is for single use only. The extension set may be used for direct injection, intermittent infusion, continuous infusion or aspiration. Pressure Rated: The Carefusion NeutraClear™ multi-fuse Extension Set with needle-free connector is for single use only. The	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. 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,	Equivalent

	extension set can 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.	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.	
Needless Connector	Carefusion NeutraClear™ Needle-free connector EL-NC1000	CareFusion MZ1000, (K132413)	Different
Maximum injection pressure	325psi	325psi	Equivalent
Components	Tubing, Luer, Needle-free connector, male spin lock, bifurcated connector, stopcock	Tubing, Luer, Needleless connectors, Male Spin Lock , bifurcated connector	Equivalent
Sterilization Method	Ethylene Oxide	E-beam (Radiation)	Different
Single patient use	Yes	Yes	Equivalent
Duration of use	7 days 200 activations	7 days 200 activations	Equivalent
Provided Sterile	Yes	Yes	Equivalent

VI. **Performance Data**

The following FDA recognized performance standards and guidance were performed in evaluating the functionality of Carefusion NeutraClear™ multi-fuse Extension Set with needle-free connector(s):

- ISO 8536-4:2013 Infusion equipment for medical use- Part 4: Infusion set for single use, gravity feed
  ISO8536-8:2015 Infusion equipment for medical use - part 8 : Infusion sets for single 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
  ISO8536-10:2015 applies to sterilized infusion set for single use for use with pressure infusion equipment up to maximum of 200kPa (2 bar)
    - Particulate contamination
    - Tensile strength
    - Filter for fluid
    - Infusion liquid flow rate
    - Absence of air bubble

- Leakage test
- Test of 200 connections and disconnections
- Alcohol: alcohol-resistant
- Lipids : Lipid-resistant 7 days
- Disinfection with isopropyl alcohol 70% (disinfection of valve)
- Resist to 325psi for the pressure rated extension sets

- ISO594-1:1998 Conical fittings with 6%(luer) taper for syringes, needles, and certain other medical equipment – Part 1 General requirements
  ISO594-2:1998 Conical fittings with 6%(luer) taper for syringes, needles, and certain other medical equipment – part 2 Locking fittings
  - Dimensions of male and female connectors in accordance with the table and diagrams in standard ISO594-1
  - Liquid leaks
  - Air leaks
  - Force of separation
  - Unscrewing torque
  - Resistance to thread stripping
  - Cracks due to pressure

- ISO14971:2013 Medical devices- Quality management systems- Requirements for regulatory purposes

- ISO 10993-1:2009, Biological evaluation of medical devices – part 1: Evaluation and testing within a risk management process
  - Cytotoxicity
  - Intracutaneous injection
  - Systemic injection
  - Sensitization (Kligman Maximization Test)
  - Hemolysis
  - Hemocompatibility
  - Pyrogenicity test
  - Particulate contamination
  - Limulus Amebocyte Lysate test (endotoxin)
  - Extractable and leachable agent extraction test

- ISO 11135:2007 Standard: "Sterilization of Healthcare Products - Ethylene Oxide" : validation of the sterilization process with ethylene oxide according to the half-cycle method
  - Bioberdum test
  - Sterility Test

  - EOR and ECH residual tests

- ISO 11607 Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems -- Part2: Validation requirements for forming, sealing and assembly processes
  - Sterility barrier after aging

The following functional performance testing has been carried out to demonstrate that the device performs as intended:

- Microbial ingress and barrier testing (FDA Guidance for Industry and FDA Staff : Intravascular Administration Sets Premarket Notification Submission [510(k)])
- Hemolysis testing (ISO 10993-4)
- Shelf life performance testing (ISO 8536-4, ISO 8536-10, ISO 11607-1, ISO 11607-2)
- Harsh Infusates testing (ISO 8536-4, ISO 8536-10)
- Priming volume (dead volume)/ flow rate testing (ISO 8536)
- Sterilization validation testing (ISO 11135)
- Pressure resistance testing (internal testing method)

A sterilization validation has been performed and a shelf life testing has been conducted.

VII. Sterilization

The subject device is Ethylene oxide sterilized. Sterilization is performed according to the requirements of the ISO 11135-1"2007 and ISO 10993-7:2008.

VIII. Shelf life

The subject device has a shelf life of 3 years.

IX. Conclusions

The results of the non-clinical testing exhibited that Carefusion NeutraClear™ multi-fuse Extension Set with needle-free connector(s) met the acceptance criteria for all functional, microbial ingress, sterility, biocompatibility and other performance criteria, which verify it to be substantially equivalent to the predicate devices.