DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 1, 2017

Cair L.G.L
Delphine Molinari
Official Correspondent
1, Allée des Chevreuils Parc Tertiaire de Bois Dieu
69380 Lissieu
FRANCE

Re: K171117
Trade/Device Name: Carefusion NeutraClear™ Needle-free connector (EL-NC1000)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: August 7, 2017
Received: August 21, 2017

Dear Ms. 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" (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 A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171117

Device Name
Carefusion NeutraClear™ Needle-free Connector

Indications for Use *(Describe)*
Carefusion NeutraClear™ Needle-free Connector is a bidirectional valve allowing injections and infusions to be given or sample taken via an intravenous line; or samples taken via arterial line. It seals and protects the line when it is not activated. The NeutraClear™ needle-free connector may be used with low-pressure power injectors procedures to a maximum pressure of 325psi with a flow at 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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510k Summary

I. Submitter's Identification

Submitter Name: Cair L.G.L
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E-mail: dmolinari@cairlgl.fr
Date of Preparation: August 29, 2017

II. Identification of the device

Subject Device

Trade Name: Carefusion NeutraClear™ needle-free connector (EL-NC1000)
Common Name: Bidirectional needleless injection valve
Regulation Name: Intravascular administration set
Product Code: FPA
Regulation: 21 CFR 880.5440
Device Class: II
510k Number: K171117

Predicate Device

Trade name: NeutraClear ™ (EL200 transparent variance)
Common Name: Bidirectional needleless injection valve
Classification Name: Intravascular administration set
Product Code: FPA
Regulation: 21 CFR 880.5440
Device Class: II
510k Number: K133073

III. Device Description

Carefusion NeutraClear™ Needle-free connector is a sterile, non-pyrogenic bidirectional needleless injection valve intended for single patient use as an accessory to intravascular administration sets allowing infusions to be given or samples taken via an intravenous line or via arterial line without using a needle, thus eliminating the potential for needle-stick injuries during use. It seals and protects the line when it is not activated. This bidirectional needleless injection valve may be used with low-pressure power injectors to a maximum pressure of 325psi with a flow at 10mL per second. The Carefusion NeutraClear™ can be used for up to 200 activations or 7 days.

IV. Indication for Use

Carefusion NeutraClear™ Needle-free connector is a bidirectional valve allowing injections and infusions to be given or sample taken via an intravenous line; or samples taken via arterial line. It seals and protects the line when it is not activated. The Carefusion NeutraClear™ needle-free connector may be used with low-pressure power injectors procedures to a maximum pressure of 325psi with a flow at 10mL per second.

V. Technological Characteristics

The subject device, Carefusion NeutraClear™ Needle free connector and predicate device, NeutraClear EL200 are both bidirectional needleless injection valves for administration or withdrawal of fluids from a patient through a cannula placed in the vein or for withdraw of blood through the artery. The subject device may be used with low-pressure injectors with a maximum pressure of 325 psi and a flow rate of 10ml per second.

Please see below for a comparison table of the Carefusion NeutraClear™ Needle free connector to the predicate device.

	Subject Device	**Predicate Device**	
Technological Characteristics	**Carefusion NeutraClear ™ Needle-free connector EL-NC1000**	**NeutraClear EL200**	**Substantial Equivalence**
Product Description	Bidirectional needleless valve with a permeable protective cap in Polyethylene	Bidirectional needleless valve without a protective cap	Different
Indications for Use	Carefusion NeutraClear™ Needle-free connector is a bidirectional valve allowing injections and infusions to be given or sample taken via an intravenous line; or samples taken via arterial line. It seals and protects the line when it is not activated. The Carefusion NeutraClear™ needle-free connector may be used with low-pressure power injectors procedures to a maximum pressure of 325psi with a flow at 10mL per second.	NeutraClear™ bidirectional needleless injection valve is a single use, sterile, non-pyrogenic device intended for use as an accessory to intravascular administration sets for the administration or withdrawal of fluids from a patient through a cannula placed in the vein or for withdraw of fluids through the artery. Bidirectional needleless injection valve may be used with low-pressure power injectors with a flow at 10ml/s, in state of connection.	Different
Material	Housing: Polycarbonate Seal: Silicone Ring: Polyoxymethylene Lubricant: Silicone	Housing: Polycarbonate Seal: Silicone Ring: Polyoxymethylene Lubricant: Silicone	Equivalent
Material of protective cap	Polyethylene	N/A	Different
Single-use	Yes	Yes	Equivalent
Sterilization method	Ethylene oxide	Ethylene oxide	Equivalent
Shelf life	3 years	3 years	Equivalent
Environmental of Use	General Hospital	General Hospital	Equivalent

	Subject Device	Predicate Device	
Technological Characteristics	**Carefusion NeutraClear ™ Needle-free connector EL-NC1000**	**NeutraClear EL200**	**Substantial Equivalence**
Technology and design	When activated by a male Luer, a pre slit elastomeric sleeve advances over an internal post, opening a fluid pathway that connects the female and male ends of the device.	When activated by a male Luer, a pre slit elastomeric sleeve advances over an internal post, opening a fluid pathway that connects the female and male ends of the device.	Equivalent
Compatibility with Chlorhexidine	Yes	No	Different
Flush Volume	2.5 ml	10 ml	Different
Maximum injection pressure	325psi	7 bars	Different
Priming Volume (Dead Volume)	0.049ml	0.05ml	Equivalent
Duration of use	7 days 200 activations	7 days 400 activations	Different

Explanation of Similarities and Differences Technological Characteristics compared to Predicate Device

The Subject device, Carefusion NeutraClear™ Needle-free connector have the following similarities to the predicate device:

- Principle of operation
- Same technology and design
- Same configuration
- Same materials used
- Same sterilization method
- Same performance specifications

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

These additional characteristics are verified and validated by testing to demonstrate the subject device is sufficient for its intended use and therefore substantially equivalent to the

predicate device. The additional characteristics do not raise different questions of safety or effectiveness.

- A permeable protective cap is added to the predicate device. The cap is made of Polyethylene and will not contact the fluid path of the device.
- Compatibility with Chlorhexidine
- Increase maximum injection pressure rate to 325 psi for use with power injector
- Flush Volume: clears fluid path with 2.5ml of saline
- Duration for Use up to 7 days or 200 activations
- New Indication for Use introduced to the subject device for using with a low-pressure power injectors procedures to a maximum pressure of 325 psi with a flow at 10 ml per second.

VI. Performance Data

The following FDA recognized performance standards and guidance were performed in evaluating the functionality of Carefusion NeutraClear™ needle-free connector EL-NC1000:

- ISO 8536-4:2013 Infusion equipment for medical use- Part 4: Infusion sets for single use, gravity feed
- ISO594-2:1998 Conical fittings with 6%(luer) taper for syringes, needles, and certain other medical equipment – part 2 Locking fittings
- ISO8536-10:2015 applies to sterilized infusion sets for single use for use with pressure infusion equipment up to maximum of 200kPa (2 bar)
- ISO14971:2013 Medical devices- Quality management systems- Requirements for regulatory purposes
- ISO 10993-1:2010, Biological evaluation of medical devices – part 1: Evaluation and testing within a risk management process
- ISO 11135:2007 : "Sterilization of Healthcare Products - Ethylene Oxide" : validation of the sterilization process with ethylene oxide according to the half-cycle method
- 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
- ISO 10993-4 Hemolysis Testing: Biological Evaluation of Medical Devices-Part 4 Selection of tests for interactions with blood

The following additional functional performance testing has been carried out to demonstrate that the device performs as intended based on internal specification and test methods.

- Liquid leak-open/closed position (Internal Test Method)
- Vacuum leak- open/closed position (Internal Test Method)
- Microbial Ingress testing
- Pressure Resistance Testing (Internal Test Method)
- Flushing Volume (Internal Test Method)
- Compatibility with Chlorhexidine (Internal Test Method)

VII. Conclusions

The results of the non-clinical testing and risk analysis assessment exhibited that no new questions of safety and efficacy are raised with the proposed introduction of Carefusion NeutraClear™ EL-NC1000. The device 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 device.