510k Summary

I. Submitter's Identification

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II. Identification of the device

Subject Device

Trade Name: Carefusion NeutraClear™ Needle-free connector (EL-NC1000A)
Common Name: Bidirectional needleless injection valve
Classification Name: Intravascular administration set
Product Code: FPA
Regulation: 21 CFR 880.5440
Device Class: II

Predicate Device

Trade Name: NeutraClear™ (EL 200 transparent variances)
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. Reason of submission

1) New commercial name
2) New reference number
3) Add a protective cap

IV. Device Description

Carefusion NeutraClear™ Needle-free connector is a bidirectional needleless injection valve. The Carefusion NeutraClear™ Needle-free connector 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. Carefusion NeutraClear™ Needle-free connector may be used with low-pressure power injectors with a flow at 10 ml/s, in state of connection.

Carefusion NeutraClear™ Needle-free connector is intended for single patient use in intravenous and blood administration sets without need for needles, thus eliminating the potential for needle-stick injuries during use. The subject device is not intended to treat existing infections. The device is not intended to have any effect on contaminated infusion solutions.

V. Indication for Use

Carefusion NeutraClear™ Needle-free connector 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. Carefusion NeutraClear™ Needle-free connector maybe used with low-pressure power injectors with a flow at 10 ml/s, in state of connection.

VI. Technological Characteristics

The subject device, Carefusion NeutraClear™ Needle free connector, has the same indication for use as predicate device, NeutraClear™ EL200. They are bidirectional needleless injection valves for administration or withdrawals of fluids from a patient through a cannula placed in the vein or for withdraw of fluids through the artery. The subject device and predicate devices may be used with low-pressure injectors with a flow rate of 10ml per second. The subject device is identical or similar in

principles of operation, technology and design, configuration, materials, sterilization method, performance specifications as the predicate device.

The subject device has a permeable protective cap added to the predicate device. The cap is made of Polyethylene and will not contact the fluid path of the device. The additional feature is verified and validated by testing to support the subject device is sufficient for its intended use and therefore substantially equivalent to the predicate device.

Substantial equivalence table

	Subject Device	**Predicate Device**	
Technological Characteristics	**Carefusion NeutraClear ™ Needle-free Connector EL-NC1000A**	**NeutraClear™ EL200** (K133073)	**Substantial Equivalence**
Product Name	Carefusion NeutraClear™ Needle-free connector	NeutraClear ™	Difference New product name, new reference number given to differentiate the device with the protective cap
Product reference number	EL-NC1000A	EL200	
Product Description	Bidirectional needleless injection valve with a protective cap	Bidirectional needleless injection valve	Difference New component added - Protective cap is added

	Subject Device	**Predicate Device**	
Technological Characteristics	**Carefusion NeutraClear ™ Needle-free Connector EL-NC1000A**	**NeutraClear™ EL200** (K133073)	**Substantial Equivalence**
Intended use	Intended for single patient use in intravenous and blood administration sets without need for needles, thus eliminating the potential for needle-stick injuries during use. The subject device is not intended to treat existing infections. The device is not intended to have any effect on contaminated infusion solutions	Intended for single patient use in intravenous and blood administration sets without need for needles, thus eliminating the potential for needle-stick injuries during use. The subject device is not intended to treat existing infections. The device is not intended to have any effect on contaminated infusion solutions	Equivalent
Indications for use	Carefusion NeutraClear™ Needle-free connector 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. Carefusion NeutraClear™ Needle-free connector may be used with low-pressure power injectors with a flow at 10ml/s, in state of connection.	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.	Equivalent
Maximum injection pressure	100 psi	100 psi	Equivalent
Material	Housing: Polycarbonate Seal: Silicone Ring: Polyoxymethylene Lubricant: Silicone	Housing: Polycarbonate Seal: Silicone Ring: Polyoxymethylene Lubricant: Silicone	Equivalent
Material of cap	Polyethylene	N/A	Difference New cap added to subject device
Contacting Materials	Blood path indirect , with an IV solution or blood	Local , with an IV solution or blood	Equivalent
Single-use	Yes	Yes	Equivalent
	Subject Device	**Predicate Device**	

Technological Characteristics	**Carefusion NeutraClear ™ Needle-free Connector EL-NC1000A**	**NeutraClear™ EL200** (K133073)	**Substantial Equivalence**
Provide Sterile	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
Intended users	Adult and pediatrics	Adult and pediatrics	Equivalent
Principles of operation	The female Luer valve opens to permit the introduction or withdrawal of fluids when accessed by a male Luer tip. This access deforms a compressible element that returns to its original shape through the mechnical properties of the deformable element.	The female Luer valve opens to permit the introduction or withdrawal of fluids when accessed by a male Luer tip. This access deforms a compressible element that returns to its original shape through the mechnical properties of the deformable element.	Equivalent
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
Duration of use	7 days	7 days	Equivalent

VII. Performance Data

The following FDA recognized performance standards and guidance were performed in evaluating the functionality of NeutraClear EL-NC1000A:

- ISO 8536-4:2010 Infusion equipment for medical use- Part 4: Infusion sets for single use, gravity feed
- ISO 594-2:1998 Conical fittings with 6%(luer) taper for syringes, needles, and certain other medical equipment – part 2 Locking fittings
- ISO8536-10:2004 applies to sterilized infusion sets for single use for use with pressure infusion equipment up to maximum of 200kPa (2 bar)
- ISO 10993-1:2009, Biological evaluation of medical devices – part 1: Evaluation and testing within a risk management process

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

- Microbial ingress testing
- Hemolysis testing
- Priming volume/ flow rate testing

VIII. 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.

IX. Shelf life

The subject device has 3 years of shelf life.

X. Risk Management

The assessment of risk analysis for modifications made to the subject device was conducted in accordance with ISO 14971:2013 did not raise new issues of safety or effectiveness.

XI. Conclusions

The results of the non-clinical testing and risk analysis assessment exhibited that the device met the acceptance criteria for all functional, microbial ingress, sterility, biocompatibility and other performance criteria. The conclusions drawn from the non-clinical tests demonstrate that Carefusion NeutraClear ™ Needle-free connector (EL-NC1000A) is as safe and as effective and performs as well as the legally marketed predicate devices.