Section 5 - 510(k) Summary K133073

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

5.1 - Submitter's Identification

Company name:	CAIR L.G.L.
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Prepared:	09/06/2013
Revised:	Not applicable

5.2 - Identification of the device

Trade name 1:	Cair Drive (EL 500 orange variance)
Trade name 2:	Neutraclear (EL 200 transparent variance)
Common Name:	Bidirectional needleless injection valve
Regulation Name:	Intravascular administration set
Regulation Number:	21 CFR 880.5440
Product Code:	FPA
Regulatory Class	II

5.3 - Indications for Use (Cair Drive and 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 10 ml/s, in state of connection.

5.4 - Identification of Equivalent Legally Marketed Device

Device Trade name	Regulation Number	Regulatory Class	Product code	510k number	Classification Name	Decision date
Arisure Neutral Valve Yukon medical	21 CFR 880.5440	II	FPA	K120799	Intravascular administration set	03/30/2012

Table 5.4.1: Identification of Equivalent Legally Marketed Device

Legally marketed device	510k number	Intended use	Predicate Device
Arisure Neutral Valve Yukon medical	K120799	The Arisure Neutral 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 artery.	Predicate Device MicroCLAVE® B3300 Connector and CLAVE® C 1000 Connector (510(k):K970855)

Table 5.4.2: Intended use and predicate device

The indication for use of the Cair bidirectional needleless injection valve (Cair Drive and Neutraclear) is equivalent to the legally marketed device chosen as a predicate device. The Cair bidirectional needleless injection valve (Cair Drive and Neutraclear) is substantially equivalent, with respect to questions of safety and effectiveness, to the predicate Arisure Neutral Valve Yukon medical.

Cair bidirectional needleless injection valve 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.

5.5 - Description of the device and Technological Characteristics

The CAIR LGL valves features include a smooth swappable septum surface, septum seal integrity with no gaps or openings, a microbial physical barrier, straight through fluid pathway, zero dead space, zero fluid displacement low priming volume, saline-only flush option and no clamping sequence or positive pressure syringe technique required.

The Cair bidirectional needleless injection valve may be used with low pressure power injectors having a pressure of 7 bars with a luer lock connection.

5.5.1 - Device Characteristics

Software	The Cair bidirectional needleless injection valve does not include a software.
Biologics	The Cair bidirectional needleless injection valve does not include biologics.
Drugs	The Cair bidirectional needleless injection valve does not include drugs.
Patient Contacting Materials	The Cair bidirectional needleless injection valve is non-invasive. The type of contact is a local contact with IV solution and blood.
Coatings	The Cair bidirectional needleless injection valve does not include coatings.
Additives	The Cair bidirectional needleless injection valve does include bisphenol (plastifier). Cair Drive (EL 500 variance) includes orange dyer. Cair Drive and Neutraclear do not include phtalates and are latex free.
Single-use	The Cair bidirectional needleless injection valve is single use.
Sterile	The Cair bidirectional needleless injection valve is sterile.
Sterilization Method	The Cair bidirectional needleless injection valve are sterilized by ethylene oxide in accordance with the ISO 11135:2007: "Sterilization of Healthcare Products - Ethylene Oxide" standard.

Environment Of Use General Hospital

5.5.2 - Materials of Use

The subject device is composed of materials (polycarbonate, silicone) that have been successfully and safely used in medical devices including the predicate device. The materials used in the subject device have been subjected to and passed biocompatibility testing.

5.6- Safety and Effectiveness, comparison to the predicate device

This subject device, Cair bidirectional needleless injection valve (Cair Drive and Neutraclear) and predicate device are substantially equivalent: they have the same intended use and indication for use. Technological and performance differences (refer to close 5.7 of this section) do not raise any new questions of safety or effectiveness. Comparison analysis, including comparison tables, of the subject device versus the predicate device are provided in the section below.

5.7– Comparison summary

	Table 5.7: Comparison summary	
	Subject Device **Cair bidirectional needleless injection valve** *(Neutraclear and Cair Drive)*	**Predicate device** **Arisure Neutral Valve** **K120799**
Materials	Lower Housing (Internal Conduit) - Polycarbonate Pre-slit Silicone Piston: silicone rubber Lubricant – Fluorosilicone Upper Housing - Polycarbonate Retention Ring- Polyoxymethylene	Lower Housing (Internal Conduit) - Polycarbonate Pre-slit Silicone Piston: silicone rubber Lubricant - Fluorosilicone Upper Housing - Polycarbonate Retention Ring- Polycarbonate
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 mechanical 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 mechanical properties of the deformable element.
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.

Table 5.7: Comparison summary

5.8-Statement of substantial equivalence

Cair bidirectional needleless injection valve (Cair Drive and Neutraclear) is substantially equivalent with the predicate device identified in the table 5.7: Comparison summary.

5.9-Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence

The following non-clinical tests have been done to support the substantial equivalence of the Cair bidirectional needleless injection valve (Cair Drive and Neutraclear) to the predicate Arisure Neutral Valve device:

- Microbial Ingress Testing
- Biocompatibility Testing
- Liquid Leak (open position)
- Liquid Leak (closed position)
- Vacuum Leak (open position)
- Vacuum Leak (closed position)
- Flow Rate
- Tensile Strength
- Disconnection Bolus

Results from non-clinical testing indicate that the Cair bidirectional needleless injection valve (Cair Drive and Neutraclear) is as safe and effective as the predicate device. Testing conducted, that reference the design verification and validation testing of the Cair bidirectional needleless injection valve (Cair Drive and Neutraclear), meets pre-determined acceptance criteria for the device. Testing conducted as a direct comparison of the Cair bidirectional needleless injection valve (Cair Drive and Neutraclear) and predicate device demonstrate the substantial equivalence of the devices.

In addition the following standards have been used for the design of the Cair bidirectional needleless injection valve (Cair Drive and Neutraclear):

- ISO 8536-4 Fifth edition 2010-10-01 Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed - Recognized Consensus Standards (FPA)

- ISO 594-2:1998 Conical fittings with 6% (Luer) taper for syringes, needles, and certain other medical equipment – part 2 Lock fittings

- ISO 8536-10:2004 applies to sterilized infusion sets for single use for use with pressure infusion equipment up to a maximum of 200 kPa (2 bar).

- ISO 14971 : 2007 Medical devices -- Application of risk management to medical devices

- ISO 13485 : 2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes

- ISO 10993 : Biological Evaluation of Medical Devices

5.10- Discussion of Clinical Tests Performed

A literature review (scientific and bibliographic data) was conducted for the clinical assessment of the Cair bidirectional needleless injection valve (Cair Drive and Neutraclear). This review demonstrates clinical evidence of the Cair bidirectional needleless injection valve (Cair Drive and Neutraclear).

5.11- Conclusions

Based on the information provided in this submission we conclude that the Cair bidirectional needleless injection valve (Cair Drive and Neutraclear) is substantially equivalent to the predicate and is safe and effective for its intended use and indication for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 20, 2014

Wiesen Law Offices
Mr. Irving Wiesen
C/O CAIR L.G.L.
420 Lexington Avenue, Suite 2400
New York, NY 10170

Re: K133073
Trade/Device Name: Cair Drive (EL 500 orange variance)
Neutraclear (EL 200 transparent variance)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: February 18, 2014
Received: February 18, 2014

Dear Mr. Wiesen:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
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Center for Devices and
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
Not assigned yet

Device Name
Cair Drive (EL 500 orange variance) / Neutraclear (EL 200 transparent variance)

Indications for Use *(Describe)*
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 10 ml/s, in state of connection.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman
Date: 2014.03.20 11:19:22 -04'00'