MAR 2 0 2007

K070532

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Special 510(k) Summary

Name of Submitter: ICU Medical, Incorporated
4455 Atherton Drive
Salt Lake City, Utah 84123

Manufacturer and Establishment Registration Number:

Manufacturer:	***Sterilization Site:***
ICU Medical (Utah), Inc 4455 Atherton Drive Salt Lake City, Utah 84123 Site Registration Number: 1713468	Establishment ICU Medical de Mexico, S.A. de C.V. Avenida Cuarzo #250 Colonia Rancho Santa clara El Valle de Maneadero Ensenada, B.B., MEXICO 22790 Site Registration Number: 9617594
Or	
N/A	Beam-One LLC 9020 Activity Rd., suite D San Diego, California 92126 Site Registration Number: 2030598

Proprietary or Trade Name of Proposed Device: Spiros™

Common Name: Closed Male Luer

Device Classification: Class II

ProCode: FPA

Performance Standards: No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for set, administration, intravascular. Set, administration, intravascular are regulated within 21 CFR 880.5440.

Intended Use / Indications for Use: The Spiros, a CML, is a single use, sterile, non-pyrogenic, swab-able, bi-directional valve device intended for use as an accessory to an Intravascular Administration Set. The Spiros provides access for the administration of fluids from a container to a patient's vascular system through the administration needle or catheter (which is inserted into the vein or artery).

Proposed Device Description: The Spiros is a closed connector which is compatible with and used to access, standard female luers and known needle-free connectors. The Spiros is a normally closed design which will prevent the leakage of fluid or ingress of air when in the inactivated state. When activated the luer is an open two-way conduit for fluid flow. The Spiros will be an accessory to an IV administration device including tubing sets and syringes, such that an integral female luer is used to connect to such devices.

Summary of Substantial Equivalence:

Similarities:

1. The predicate and subject devices have the same intended use.
2. The predicate and subject devices have the same indications for use.
3. The predicate and subject devices contain the components made from the same materials with the one exception noted below.

Differences:

1. The subject device will use a Polycarbonate material from a different vendor than the predicate device. This material is used on another legally marketed device by ICU Medical, Inc.
2. The subject device contains two internal o-ring seals while the predicate device contains one internal o-ring seal
3. The subject device contains a female luer ultrasonically welded to it; the predicate device contains a female luer that is solvent bonded to a short piece of tubing which is in turn solvent bonded to the device.

Statement of Safety and Effectiveness:

The Spiros™ closed male luer device has been tested post sterilization and passed all acceptance criteria. The Spiros™ closed male luer meets the functional claims and intended use as described in the product labeling and is safe and effective in terms of substantial equivalence as the predicate device described in this document.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Martin Maier
Senior Quality Assurance Engineer
ICU Medical, Incorporated
4455 Atherton Drive
Salt Lake City, Utah 84123

MAR 2 0 2007

Re: K070532
Trade/Device Name: Spiros™
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: February 23, 2007
Received: February 26, 2007

Dear Mr. Maier:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070532
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Indications for Use

510(k) Number (if known): _____

Device Name: Spiros™

Indications for Use: The Spiros™ is a single use, sterile, non-pyrogenic, swab-able, bi-directional valve device intended for use as an accessory to Intravascular Administration Set. The Spiros™ provides access of the administration of fluids from a container to a patient's vascular system through the administration needle or catheter (which is inserted into the vein or artery).

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 3/19/07 for ADW

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

(Division Sign-Off) K070532