K082806

ICU MEDICAL INC.
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Preparation Date: April 06, 2009

APR - 3 2009

ICU Medical, Inc.

APR - 6 2009

SPECIAL 510(K) Summary of Safety and Effectiveness for the:

Trade Name: Spinning Spiros

Common Name: Accessory to Piston Syringe, Needleless

Classification Name: I.V. Administration Set, Accessory 21 CFR 880.5440, Class II Device

Product Code: FPA

Legally Marketed Predicate Devices for Substantial Equivalence:

*K070532 – Spiros – ICU Medical, Inc.

Rationale for SE:

The Spinning Spiros device is a passively closed – closed male luer or CML. This device is equivalent to the predicate device because it does not modify the claim. The few dimensional changes are necessary for larger cavity molds and for eventual automated assembly. The spin collar adds the feature that the Spinning Spiros won't accidentally back off of a syringe.

Description of Submitted Device:

The Spinning Spiros is a closed connector which is compatible with and used to access, standard female luers and known needle-free connectors. The Spinning Spiros is a passively closed design which will prevent the leakage of fluid or ingress of air when in the inactivated (resting) state. When activated the luer is an open two-way conduit for fluid flow. The Spinning Spiros is 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.

Intended Use:

The Spiros is a single use, sterile, non-pyrogenic, swab-able, bidirectional 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).

Safety and Performance:

ICU Medical Spinning Spiros closed male luer device has been tested post sterilization and passed all acceptance criteria. The Spinning 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.

Conclusion:

The materials, performance, and operational features of both the submitted device and the predicate devices are substantially equivalent and safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Tracy Best
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4455 Atherton Drive
Salt Lake City, Utah 84123

APR - 6 2009

Re: K082806
Trade/Device Name: Spinning Spiros
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: March 9, 2009
Received: March 10, 2009

Dear Mr. Best:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Charles A. Murphy for S. Runner, DDS

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082806

Device Name: Spinning Spiros

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Prescription Use __XX___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K082806