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APR 16 2007

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 Sites:*
ICU Medical (Utah), Inc 4455 Atherton Drive Salt Lake City, Utah 84123 Site Registration Number: 1713468	Sterigenics US, Inc – Utah 5725 West Harold Gatty Drive Salt Lake City, Utah 84116 Site Registration Number: 1721676
Or	
N/A	Steris Isomedix 7685 St. Andrews Ave San Diego, California 92154 Site Registration Number: 2032112

Proprietary or Trade Name of Proposed Device: The ICU Medical Dye Management® System.

Common Name: Catheter lab kit, angiography kit, dye management set.

Device Classification, Pancode and ProCode: Class II, 74 – DQO

Performance Standards: No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Diagnostic Intravascular Catheters. Dye Management® sets are regulated within 21 CFR 870.1200.

Intended Use / Indications for Use: Indicated for Contrast Media Administration in Angiographic procedures.

Proposed Device Description: The Dye Management® System is comprised of two (2) components namely; 1) a dye management set with contrast spikes. 2) A dye management set with in-line reservoir. The Dye Management® system is configured by attaching the reservoir set to either the one (1) or two (2) spike set.

Summary of Substantial Equivalence:

Similarities:

1. The current and proposed sets have the same intended use
2. The current and proposed sets are assembled for customer convenience using currently manufactured components.
3. The current and proposed sets contain the same type of components.

Differences:

1. An alternate burette, made of different materials and construction, is being added for use in the assembly of this set.

Statement of Safety and Effectiveness:

The alternate Burette has been tested post sterilization and passed all acceptance criteria. The Dye Management System™ 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 set(s) described in this document.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 16 2007

ICU Medical, Inc.
c/o Mr. Martin Maier
Senior QA Engineer
4455 Atherton Dr.
Salt Lake City, UT 84123

Re: K063784
Dye Management System™
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: II
Product Code: DQO
Dated: March 15, 2007
Received: March 19, 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) 276-0120. 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,

Donna R. Volkmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K063784

Indications for Use

510(k) Number (if known): _____

Device Name: Dye Management System™

Indications for Use: The Dye Management® System is indicated for Contrast Media Administration in Angiographic procedures.

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)

Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K063784