K052865

DEC 2 2 2005

Special 510(k) Summary

Name of Submitter:

Hospira, Incorporated
275 North Field Drive
Lake Forest, Illinois 60045
Owner/Operator #: 9063339

Manufacturer and Establishment Registration Number:

Manufacturer:	**Sterilization Site:**
ICU MEDICAL (UTAH), INC. 4455 Atherton Dr. Salt Lake City, UT 84123 Establishment Registration #: 1713468	Sterigenics US, INC – Utah 5725 West Harold Gatty Drive Salt Lake City, UT 84116 Establishment Registration #: 1721676 OR Sterigenics US, INC – NM 2400 Airport Road Santa Teresa, NM 88008 Establishment Registration #: 1721686

Proprietary or Trade Name of Proposed Device: HOSPIRA CathLab Convenience Kits

Common Name: CathLab Kit / Convenience Kit, Diagnostic Intravascular Catheter.

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. Convenience kits are regulated within 21 CFR 870.1200.

Intended Use / Indications for Use:
The HOSPIRA CathLab Convenience Kits are intended for use in cardiac catheterization and radiology procedures requiring the use of contrast media. These procedures include right heart studies, venogram and arteriogram. The kit provides the user with a "ready-to-use" set up avoiding the need to acquire / assemble components from various manufacturers. The kit is intended for one-time use.

The intended use of the antiseptic contained within a kit is to prepare the patient's skin prior to surgery.

Proposed Device Description:
The HOSPIRA CathLab Convenience Kits are comprised of variations of the following components: Needles, guide wires, vessel dilators, slide clamps, suture wings, suture wing clips, syringes, table covers, antiseptic solutions / swab sticks / ointments, absorbent towels, gauze sponges, Lidocaine HCl injection, drapes, scalpels, silk cutting needle suture, dressings and sharps stick pads.

Summary of Substantial Equivalence

The HOSPIRA CathLab Convenience Kits as described in this submission is substantially equivalent to the predicate CARDIAC CATHETERIZATION KIT (K932141) with respect to the following characteristics:

Similarities:

1) Both kits have the same intended use.
2) Both kits are assembled for customer convenience using currently manufactured components.
3) Both kits contain the same types of components.

Differences:

1) An alternate antiseptic, ChloraPrep® antiseptic, is being added for use in the assembly of this convenience kit.

Statement of Safety and Effectiveness

The ChloraPrep® applicator has been tested after three EtO cycles and has passed all test criteria. The HOSPIRA CathLab Convenience Kits meet the functional claims and intended use as described in the product labeling, and is as safe and effective in terms of substantial equivalence as the predicate convenience kit(s) described in this document.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 2 2005

ICU Medical, Inc.
c/o Thomas Kozma, Ph.D.
Associate Director, Global Regulatory Affairs
4455 Atherton Dr.
Salt Lake City, UT 84123

Re: K052865
HOSPIRA Cath Lab Convenience Kits
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagno0stic intravascular catheter
Regulatory Class: II
Product Code: DQO
Dated: November 21, 2005
Received: November 22, 2005

Dear Dr. Kozma:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Lo Ami

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

Enclosure

Indications for Use

510(k) Number (if known) K052865

Device Name: **HOSPIRA Cath Lab Convenience Kits**

Indications for Use:

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use_____** (Part 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)

Donna R. Vochner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052865