HOSPIRA Latex-Free Critical Care and Advanced Sensor Catheters

K061450

510(k) Summary

Name of Submitter:

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

AUG - 4 2006

Manufacturer and Establishment Registration Number:

Manufacturer:	**Sterilization Site:**
ICU MEDICAL (UTAH), INC. 4455 Atherton Dr. Salt Lake City, UT 84123 Establishment Registration #: 1713468	Isomedix Operations Inc. 9120 South 150 East Sandy, UT 84070 Establishment Registration #: 1720929

Proprietary or Trade Name of Proposed Device: HOSPIRA Latex-Free Critical Care and Advanced Sensor Catheters

Common Name: Flow-Directed Catheter

Device Classification, Pancode and ProCode: Class II, 74 - DYG

Performance Standards: No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Flow-Directed Catheters regulated within 21 CFR 870.1240.

Intended Use / Indications for Use:
Hospira Latex-Free Advanced Sensor Catheters:
Indicated for the assessment of the hemodynamic status of a patient, including but not restricted to the following: Venous Pressures, Cardiac Output, Oxyhemoglobin Saturation, and Venous Blood Sampling. A secondary indication is for the therapeutic infusion of solutions.

Hospira Latex-Free Critical Care Catheters:
Indicated for the assessment of hemodynamic status through right atrial, right ventricular, and pulmonary artery and / or wedge pressure monitoring for patients including the following: acute heart failure; differentiating ruptured ventricular septum from mitral regurgitation; diagnosis of tamponade; severe hypovolemia; complex circulatory situations (e.g., fluid management with acute burn patients); medical emergencies; adult respiratory distress syndrome; gram negative sepsis; drug intoxication; acute renal failure; hemorrhagic pancreatitis; intra- and postoperative management of high risk patients; history of pulmonary or cardiac disease; fluid shifts (such as extensive intra-abdominal operations); management of high risk obstetrical patients; known cardiac disease; toxemia; premature separation of placenta; cardiac output determination by thermodilution method; and blood sampling.
Additional indication for Hospira Latex-Free Critical Care Pacing Lead Catheters:
Indicated for temporary transluminal ventricular pacing using a temporary ventricular pacing lead.

Proposed Device Description:
The HOSPIRA Latex-Free Critical Care and Advanced Sensor Catheters have multi-lumens that incorporate some or all of the following components and features: a distal balloon for positioning the catheter tip via blood flow within the pulmonary artery, a heater coil for determining continuous cardiac

HOSPIRA Latex-Free Critical Care and Advanced Sensor Catheters

output, a thermistor for monitoring core temperature and cardiac output, fiber optics for monitoring mixed venous oxygen saturation (SvO_2), and access ports for drug delivery or blood sampling. In addition, the HOSPIRA Latex-Free Critical Care Pacing Lead Catheters include an access port for use with Transluminal Right Ventricular Pacing Leads. The catheters also incorporate insertion distance markings and are provided with a syringe for inflating the latex-free balloon.

Summary of Substantial Equivalence

The HOSPIRA Latex-Free Critical Care and Advanced Sensor Catheters as described in this submission are substantially equivalent to the predicate Flow Directed Thermal-Dilution Infusion Catheter (821057), OptiCath Heparin Coated Flow-Directed Catheter (K823007), and Sorenson Thermo Flow-Directed Transluminal Pacing Catheter (K874465) with respect to the following characteristics:

Similarities:

1) The catheters have the same intended use and indications for use.
2) The catheters contain the same type of components.
3) The method of sterilization of Hospira Latex-Free Advanced Sensor Catheters is the same.

Differences:

1) The material used to manufacture the balloon in both the Critical Care Catheters and Advanced Sensor Catheters is Polyisoprene-Polyurethane compound rather than Latex Rubber.
2) Critical Care catheters will be sterilized using gamma radiation rather than EtO sterilization.

Statement of Safety and Effectiveness

The gamma sterilized Polyisoprene-Polyurethane balloon has been tested for biocompatibility and for expansion symmetry, over inflation, multiple inflations, deflation time, and burst strength and has passed all acceptance criteria. The HOSPIRA Latex-Free Critical Care and Advanced Sensor Catheters meet the functional claims and intended use as described in the product labeling, and are as safe and effective in terms of substantial equivalence as the predicate catheters described in this document.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 4 2006

Hospira, Inc.
c/o Mr. Thomas P. Sampogna
Director Global Regulatory Affairs
275 North Field Drive
Dept. 389, Bldg. H2
Lake Forest, IL 60045

Re: K061450
Trade Names: Hospira Latex-Free Advanced Sensor Catheters
Hospira Latex-Free Critical Care Catheters
Regulation Number: 21 CFR 870.1230, 21 CFR 870.1240; and, 21 CFR 870.1915
Regulation Name: Fiberoptic Oximeter Catheter, Flow-Directed Catheter; and,
Thermodilution Probe
Regulatory Class: Class II (two)
Product Code: DQE, DYG; and, KRB
Dated: June 23, 2006
Received: June 26, 2006

Dear Mr. Sampogna:

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,

B Zuckerman for

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) K061450

Device Name: **HOSPIRA Latex-Free Critical Care and Advanced Sensor Catheters**

Indications for Use:

Hospira Latex-Free Advanced Sensor Catheters:

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Additional indication for Hospira Latex-Free Critical Care Pacing Lead Catheters:

Indicated for temporary transluminal ventricular pacing using a temporary ventricular pacing lead.

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

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

B Runnells

(Division Sign-Off) **Concurrence of CDRH, Office of Device Evaluation (ODE)**
Division of Cardiovascular Devices
510(k) Number K061450