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510(k) Summary

Name of Submitter: HOSPIRA, Incorporated
275 North Field Drive
Lake Forest, Illinois 60045
Owner/Operator #: 9063339

NOV - 3 2006

Manufacturer and Establishment Registration Number:

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

Proprietary or Trade Name of Proposed Device: Opticath® Central Venous Oximetry Probe with Fluidic Seal (Heparin Coated)

Common Name: Fiberoptic Oximetry Catheter

Device Classification, Pancode and ProCode: Class II, 78-DQE

Performance Standards: No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Fiberoptic Oximetry Catheters. Fiberoptic oximeter catheters are regulated within 21 CFR 870.1230.

Intended Use / Indications for Use:
The OPTICATH® Central Venous Oximetry Probe with Fluidic Seal (Heparin Coated) is intended for measuring the oxygen saturation of blood.

The OPTICATH® Central Venous Oximetry Probe with Fluidic Seal (Heparin Coated) is indicated for the continuous *in vivo* measurement of the oxyhemoglobin saturation of blood in the central venous system ($ScvO_2$) for monitoring hemodynamic status during metabolic, respiratory, cardiovascular, and/or other physiological system(s) compromise in accordance with hospital protocols or current Clinical Standards of Practice. The probe with fluidic seal is also indicated for pressure monitoring, and infusion of fluids.

Proposed Device Description:
The Central Venous Oximetry Probes (Heparin Coated) are non-pyrogenic, sterile, single patient use, disposable oxygenation monitoring sets for use with central venous catheters for continuous monitoring of central venous oxygen saturation. The probes are manufactured from medical-grade polymers and incorporate a closed-ended fiber optic lumen at the tip to measure central venous oxygen saturation. The exterior of the proposed device is coated with Heparin using the same Heparin agent and coating method used on Oximetry Catheters being marketed by Hospira today. The method of operation is the same as the predicate OPTICATH® Central Venous Oximetry Probe with Fluidic Seal.

The Fluidic Seal is a non-pyrogenic, sterile, single patient use device that facilitates the introduction of a Central Venous Oximetry Probe into any size-compatible central venous catheter. The Fluidic Seal also maintains the relative insertion position of the oximetry probe within the central venous catheter. The Fluidic Seal consists of a lateral flush port for the administration of fluids and/or for pressure monitoring.

The subject devices are modifications of the predicate OPTICATH® Central Venous Oximetry Probe with Fluidic Seal.

The modification is to add Heparin coating to the probe and change the lead tubing material to a PE-lined polyvinyl chloride.

Both the predicate and the proposed devices can be used with marketed central venous catheters for obtaining critical cardiac performance parameters.

Summary of Substantial Equivalence

The OPTICATH® Central Venous Oximetry Probe with Fluidic Seal (Heparin Coated) as described in this submission is substantially equivalent to the predicate OPTICATH® Central Venous Oximetry Probe with Fluidic Seal with respect to the following characteristics:

Similarities:

1) Both devices have the same intended use
2) The technology and operating principles are the same for both devices
3) The materials used to manufacture the device and the sterilization is the same.

Difference:

1) The OPTICATH® Central Venous Oximetry Probe with Fluidic Seal (Heparin Coated) is heparin coated

Statement of Safety and Effectiveness

The OPTICATH® Central Venous Oximetry Probe with Fluidic Seal (Heparin Coated) meets 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 OPTICATH® Central Venous Oximetry Probe with Fluidic Seal.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2006

Hospira, Inc.
c/o Ms. Diane Rennpferd
Sr. Associate, Global Regulatory Affairs - Devices
Dept 389 Bldg H2
275 N Field Drive
Lake Forest IL 60045-5046

Re: K062999
Trade/Device Name: OPTICATH Central Venous Oximetry Probe with Seal with Heparin
Regulation Number: 21 CFR 870.1230
Regulation Name: Fiberoptic Oximeter Catheter
Regulatory Class: Class II (performance standards)
Product Code: DQE
Dated: September 29, 2006
Received: October 2, 2006

Dear Ms. Rennpferd:

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,

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) K062999

Device Name: **Central Venous Oximetry Probe with Fluidic Seal (Heparin Coated)**

Indications for Use:

The OPTICATH® Central Venous Oximetry Probe with Fluidic Seal (Heparin Coated) is intended for measuring the oxygen saturation of blood.

The OPTICATH® Central Venous Oximetry Probe with Fluidic Seal (Heparin Coated) is indicated for the continuous *in vivo* measurement of the oxyhemoglobin saturation of blood in the central venous system ($ScvO_2$) for monitoring hemodynamic status during metabolic, respiratory, cardiovascular, and/or other physiological system(s) compromise in accordance with hospital protocols or current Clinical Standards of Practice. The probe with fluidic seal is also indicated for pressure monitoring, and infusion of fluids.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062999