K061159
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510(k) SUMMARY

1. **Submitted by:**

Hospira, Inc.
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Lake Forest, IL 60045

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Contact: Thomas Kozma, Ph.D.

JUN 26 2006

2. **Date Prepared:** June 06, 2006

3. **Name/Classification of Device:** Fiberoptic Oximetry Catheter, Class II
78 DQE, 21 CFR Parts 870.1230

4. **Trade Name of Proposed Device:** OPTICATH® Central Venous Oximetry Probe with Fluidic Seal

5. **Predicate Devices:**

Device Name	510(k) Number
OPTICATH® Oximetry Catheter (ICU Medical, Hospira, Inc.)	K820674
PreSep Central Venous Oximetry Catheter (Edwards Lifesciences)	K053609

6. **Proposed Device Description:**

The OPTICATH® Central Venous Oximetry Probe is a sterile, non-pyrogenic, single use, disposable probe for use with compatible optical modules/oximeters and central venous catheters. The probe incorporates optic fibers that enable continuous *in vivo* monitoring of oxyhemoglobin saturation within circulating blood using the principle of reflection spectrophotometry.

The Fluidic Seal is a non-pyrogenic, sterile, single use accessory to the OPTICATH® Probe that facilitates the introduction of the Probe into any size-compatible central venous catheter and maintains the insertion position of the probe tip. The Fluidic Seal has a lateral flush port for pressure monitoring or for infusion of fluids.

The subject device is a modification of the predicate OPTICATH® Oximetry Catheter (K820674). The modifications include:

1) reducing the usable length of the probe and removing the guiding balloon since the probe is intended to monitor the oxyhemoglobin saturation of blood in the superior vena cava (central venous oxygen). (i.e., the additional length and

balloon that facilitate placement of the predicate catheter into the pulmonary artery are not required) and

2) addition of a Fluidic Seal, which is an accessory to the OPTICATH® Probe, that facilitates placement of the probe into a previously-inserted central catheter and maintains the position of the probe tip.

7. **Statement of Intended Use:**

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

The OPTICATH® Central Venous Oximetry Probe with Fluidic Seal 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.

8. **Summary of Technological Characteristics of New Device Compared to Predicate Devices**

The subject and predicate devices are similar in design, principle of operation, materials of construction, intended use, labeling and manufacturing processes. All modifications were evaluated by bench testing that included testing fluid flow, fluid leakage, pressure frequency response, plunger activation force, and probe drag force. *In vivo* non-clinical testing was also performed to evaluate the accuracy of oxygen saturation measurements obtained by the probe. Results of all non-clinical testing met associated acceptance criteria and did not raise new issues of safety and/or effectiveness. Therefore, the OPTICATH® Central Venous Oximetry Probe with Fluidic Seal is substantially equivalent to the predicate Oximetry Catheters.

The claim for substantial equivalence is supported by the information provided in the 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2006

Hospira, Inc.
c/o Daniel W. Lehtonen
Intertek Testing Services NA, Inc.
2307 East Aurora Road, Unit B7
Twinsburg, OH 44087

Re: K061159
Trade Name: OPTICATH® Central Venous Oximetry Probe with Fluidic Seal
Regulation Number: 21 CFR 870.1230
Regulation Name: Fiberoptic Oximeter Catheter
Regulatory Class: II (two)
Product Code: DQE
Dated: June 7, 2006
Received: June 9, 2006

Dear Mr. Lehtonen:

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.

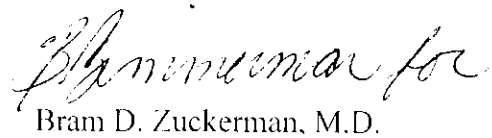
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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: K061159

Device Name: OPTICATH® Central Venous Oximetry Probe with Fluidic Seal

Indications for Use:

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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 K061159