K052828

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FEB 17 2006

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 and Sterilization Site:
Abbott - Ireland
Ballytivnan, Sligo, IRELAND
Establishment Registration #: 9610175

Proprietary or Trade Name of Proposed Device: Disposable Transpac® III Integrated Transducer (IT)
Common Name: Extravascular Blood Pressure Transducer
Device Classification, Pancode and ProCode: Class II, DRS
Performance Standards: No performance standards have been established under Section 514 of the Food, Drug, and Cosmetic Act for Pressure Monitoring Devices. An Extravascular Blood Pressure Transducer is regulated within 21 CFR 870.2850.

Intended Use / Indications for Use:
The Disposable Transpac® III Integrated Transducer (IT) is intended for direct measurement and monitoring of blood pressure. The Disposable Transpac® III Integrated Transducer (IT) is intended for one-time use.

Indications for the Disposable Transpac® III Integrated Transducer (IT) include:
Direct arterial blood pressure monitoring - central and peripheral,
Pulmonary artery monitoring,
Venous pressure monitoring,
Left atrial monitoring when used with an air eliminator filter, and
Cardiac cathterization

Proposed Device Description:
The Disposable Transpac® III Integrated Transducer (IT) is an extravascular blood pressure transducer that converts mechanical changes in pressure into electrical currents that can be input into a pressure monitor. The Disposable Transpac® III Integrated Transducer (IT) consists of an extravascular pressure transducer module that interfaces between an intravascular catheter and pressure monitor. The major components of the Disposable Transpac® III Integrated Transducer (IT) include:

- the Disposable Transpac® III Integrated Transducer (IT) module that houses a ceramic transducer,
- a Luer connector with locking collar that can connect to an intravascular catheter,
- an integrated flush valve and Luer connector that can connect a flushing fluid source to the intravascular catheter,

- a venting stopcock that can open and close the path between the intravascular catheter and transducer or flushing fluid source,
- a transducer vent port that can be opened and closed by the three-handled, venting stopcock to allow equilibration of the transducer with atmospheric pressure, and
- a transducer cable that can connect to a pressure monitor using a hooded RJ-11 connector.

The Disposable Transpac® III Integrated Transducer (IT) can be pole-mounted or patient mounted and is provided sterile and non-pyrogenic.

Summary of Substantial Equivalence

The Disposable Transpac® III Integrated Transducer (IT) is substantially equivalent to the predicate Transpac® Disposable Transducer with Monitoring Kit (K831506) with respect to the following characteristics:

Similarities:

1) The Disposable Transpac® III Integrated Transducer (IT) and predicate Transpac® Disposable Transducer with Monitoring Kit are intended for direct measurement and monitoring of blood pressure.
2) The devices are provided as non-pyrogenic and sterile and are intended for one-time use.
3) The technology and operating principles (i.e., extravascular transducer that is coupled to an intravascular pressure-monitoring catheter for converting mechanical changes in pressure into electrical currents that can be input into a pressure monitor) are the same.
4) The transducers are supplied individually or packaged within Cardiovascular Monitoring Kit.
5) Several of the materials of construction are the same, and all fluid/blood contacting materials are biocompatible based on the results of biocompatibility testing.

Differences:

1) Several of the materials of composition have been changed from the predicate devices.
2) The flush device and stopcock that were separate components of the predicate Transpac® Disposable Transducer with Monitoring Kit (K831506) have been integrated into the transducer housing of the Disposable Transpac® III Integrated Transducer (IT).

Statement of Safety and Effectiveness

The Disposable Transpac® III Integrated Transducer (IT) 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 Transpac® Disposable Transducer with Monitoring Kit device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2006

Hospira, Inc.
c/o Thomas Kozma, Ph.D.
Associate Director
Global Regulatory Affairs- Devices
275 North Field Drive
Lake Forest, IL 60045

Re: K052828
Trade Name: Disposable Transpac III Integrated Transducer (IT)
Regulation Number: 21 CFR 870.2850
Regulation Name: Extravascular Blood Pressure Transducer
Regulatory Class: Class II (two)
Product Code: DRS
Dated: January 23, 2006
Received: January 24, 2006

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,

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) K052828

Device Name: **Disposable Transpac® III Integrated Transducer (IT)**

Indications for Use:

The Disposable Transpac® III Integrated Transducer (IT) is intended for direct measurement and monitoring of blood pressure. The Transpac® III IT is intended for one-time use.

Indications for the Disposable Transpac® III IT include:

Direct arterial blood pressure monitoring - central and peripheral,
Pulmonary artery monitoring,
Venous pressure monitoring,
Left atrial monitoring when used with an air eliminator filter, and
Cardiac cathterization.

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)

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052828