K061573
p1/2

SEP 19 2006

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: Transpac® III Disposable Straight Pressure Transducer (DSPT)

Common Name: Pressure Transducer (Intracranial and Extravascular Blood)
Device Classification, Pancode and ProCode: Class II, GWM and DRS
Performance Standards: No performance standards have been established under Section 514 of the Food, Drug, and Cosmetic Act for Intracranial Pressure Monitoring Devices. An Intracranial Pressure Monitoring Device is regulated within 21 CFR 882.1620 and an Extravascular Blood Pressure Transducer is regulated within 21 CFR 870.2850.

Intended Use / Indications for Use:

The Transpac® III Disposable Straight Pressure Transducer (DSPT) is intended for direct measurement and monitoring of fluid pressure.

Indications for the Transpac® III DSPT include:
Intracranial Pressure Monitoring,
Intrauterine Pressure Monitoring, or
Compartmental (Intramuscular) Pressure Monitoring.

In addition, indications for the Transpac® III DSPT 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, or
Cardiac catheterization.

Proposed Device Description:

The Transpac® III DSPT is an extravascular pressure transducer that interfaces between a catheter and pressure monitor by converting changes in pressure into electrical currents that can be input into a compatible pressure monitor. The major components of the Transpac® III DSPT include:

- the Transpac® III Disposable Straight Pressure Transducer module that houses a ceramic transducer,
- a luer connector with locking collar that can connect to an intravascular catheter,

- a transducer cable that can connect to a compatible pressure monitor using a hooded RJ-11 connector,
- A stopcock for altering direction of fluid flow.

The Transpac® III DSPT can be pole-mounted or patient mounted and is provided sterile and non-pyrogenic and is intended for one-time use.

Summary of Substantial Equivalence

The Transpac® III DSPT is substantially equivalent to the predicate Transpac® II Disposable Transducer (K884823) and Disposable Transpac® III Integrated Transducer (IT) (K052828) with respect to the following characteristics:

Similarities:

1) The Transpac® III DSPT and predicate devices are intended for direct measurement and monitoring of pressure.
2) Indications for Use of the Transpac® III DSPT include the same Indications for Use as the predicate Transpac® II Disposable Transducer (K884823).
3) Indications for Use of the Transpac® III DSPT include the same Indications for Use as the predicate Transpac® III IT (K052828).
4) The Transpac® III DSPT and both predicate devices are provided as non-pyrogenic and sterile devices that are intended for one-time use.
5) 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 compatible pressure monitor) are the same.
6) The transducers are supplied individually or packaged within a catheter-based kit.
7) The materials of construction of the Transpac® III DSPT are the same as the predicate Transpac® III IT (K052828), and all fluid/blood contacting materials are biocompatible based on the results of biocompatibility testing.

Differences:

1) Some of the materials of construction of the Transpac® III DSPT are not identical to the materials of construction of the predicate Transpac® II Disposable Transducer (K884823); however, the materials and method of manufacture are identical to the predicate Transpac® III IT (K052828) device.
2) The size of the Transpac® III DSPT is smaller than the predicate Transpac® II Disposable Transducer but is similar to the size of the predicate Transpac® III IT (K052828)..
3) The physical appearance of the non-integrated stopcock of the Transpac® III DSPT is different from the non-integrated stopcock of the Transpac® II Disposable Transducer.

Statement of Safety and Effectiveness

The Transpac® III DSPT has been tested for biocompatibility and physical and electrical requirements and has passed all acceptance criteria. The Transpac® III DSPT 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® II Disposable Transducer and predicate Disposable Transpac® III IT devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2006

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

Re: K061573
Trade Name: Transpac® III Disposable Straight Pressure Transducer (DSPT)
Regulation Number: 21 CFR 870.2850
Regulation Name: Extravascular Blood Pressure Transducer
Regulatory Class: Class II (two)
Product Code: DRS
Dated: August 23, 2006
Received: August 28, 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 (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

K061573

Indications for Use

510(k) Number (if known) **K061573**

Device Name: Transpac® III Disposable Straight Pressure Transducer (DSPT)

Indications for Use:

The Transpac® III Disposable Straight Pressure Transducer (DSPT) is intended for direct measurement and monitoring of fluid pressure.

Indications for the Transpac® III DSPT include:

- Intracranial Pressure Monitoring,
- Intrauterine Pressure Monitoring, or
- Compartmental (Intramuscular) Pressure Monitoring.

In addition, indications for the Transpac® III DSPT 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 catheterization.

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 K061573