

	PREMARKET NOTIFICATION SPECIAL 510K	THERMODILUTION CATHETER	
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K101669

510K SUMMARY *[As required by section 807.92(c)]*

JUL - 1 2010

Amended on 24 June 2010

1. Applicant Information

Company Address: Biosensors International Pte Ltd
21 Kallang Avenue #07-165/171
Singapore 339412

Registration Number: 8043983

Contact Person: Moses Tham

Telephone: (+65) 6411 0506

Facsimile: (+65) 6298 6242

2. Device Identification

Trade Name: Thermodilution Catheter and Accessories

Classification Name: Diagnostic Intravascular Catheter

3. Predicate Devices

Thermodilution Catheter and Accessories (K083384)

4. Device Description

Biosensors flow-directed Thermodilution catheter is fabricated from extruded tubing, connected to a hub carrying 4 or 5 lumens. The total length of catheter is either of 90 or 110 cm. The extensions include a proximal, a distal, a thermistor and an inflation extension, where the distal end of the inflation extension ends with a tip mounted with a balloon.

5. Intended Use

Biosensors flow-directed Thermodilution catheter is designed for use in the critical care patients to measure right atrium, pulmonary artery and pulmonary capillary wedge pressure; continuously monitor pulmonary artery temperature, sample blood, intravenously administer drugs and solution and measure cardiac output via the cardiac output computer which interfaces with 14 kilo-ohms catheters. Different models are available for use in pediatric and adult patients.

The tips of the catheters are mounted with a latex balloon which when inflated, protects the heart tissues from the product's tips during insertion; utilizes blood flow to direct the catheter tip through the right ventricle into the pulmonary artery.

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6. Summary of Technological Characteristics of Device in relation to Predicate Devices(s)

Biosensors Thermodilution catheter product family included in 510K (K083384) is currently licensed for heparin-coated Thermodilution catheter with PVC catheter tubing and non-coated Thermodilution catheter with PU catheter tubing, mounted with natural latex balloon.

This application involves the inclusion of additional models of Thermodilution Catheter where the Thermodilution catheter is mounted with synthetic latex balloon.

Comparison is made for the above models against those that have already been licensed in K083384. The additional catheter models have the same intended use and design construction with equivalent components as the predicated catheter models which has its distal end mounted with a balloon. The safety and efficiency of the subject device models with the new balloon material type have been assessed according to the standards for preclinical testing, as listed in the below table, which are also discussed in Section 7 below.

Standard Number	Title of Standard
ISO 594/2	Conical Fittings with 6% (luer) taper for syringes, needles and certain other medical equipments – Part 2: Lock fittings
ISO10555-1	Sterile, single-use intravascular catheters – Part 1: General Requirements
ISO10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing

7. Assessment of Performance Data used to justify Substantial Equivalence

Test Summary, *In-vitro*

Models with synthetic latex balloon at distal tip

Inclusion of this category of models is to provide an alternative to physicians when handling patients who are allergic to the protein in the natural latex material.

Functionality performance tests were performed on the synthetic latex balloon mounted on the Thermodilution catheter to evaluate the performance and integrity of the synthetic latex balloon. Based on the test results which are of the accepted criteria, the synthetic latex balloon is concluded to be safe and effective for its intended use.

Test Summary, *Biocompatibility*

Biocompatibility tests were performed in accordance to ISO10993-1 Part 1: *Evaluation & Testing* and USP 27 <88> *Biological Reactivity Tests, In Vivo* and was proven that the Thermodilution catheter, with synthetic latex balloon, is biocompatible and safe for its intended use.

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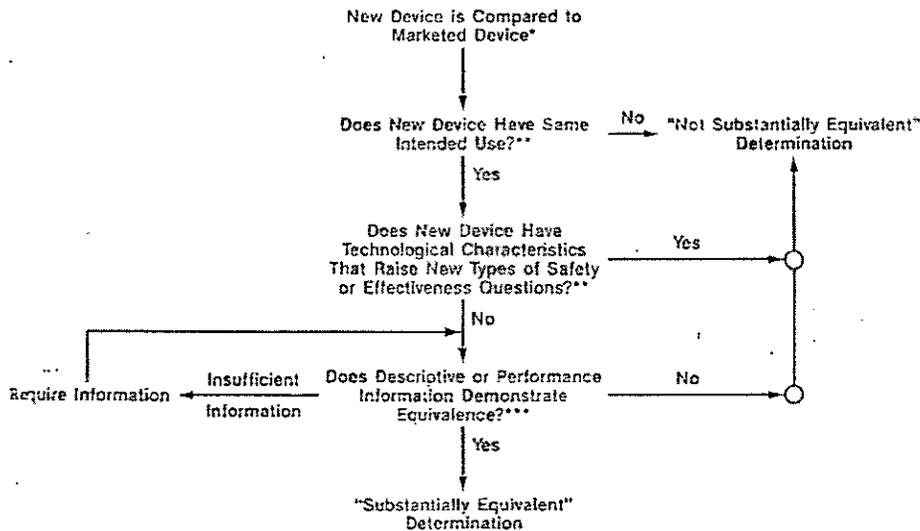
8. Conclusion:

The Functionality Tests and Biocompatibility tests have demonstrated that the Biosensors Thermodilution catheter that is substantially equivalent to the predicated devices is safe and effective for its intended use.

510K Substantial Equivalence Decision-Making Tree

ATTACHMENT I

**510(k) "Substantial Equivalence"
Decision-Making Process (Overview)**



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Device is Unclear.
 ** This Decision is Normally Based on Descriptive Information Alone, But Limited Testing Information is Sometimes Required.
 *** Data May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

Decision to substantial Equivalence is based on 510(k) Memorandum #K86-3, 510(k).

Questions in the decision path are evaluated as follow:

Q1. Does New Device have same intended use?

Yes. The intended use of the new range of models is the same as the models currently listed.

Q2. Does New Device have Technological Characteristics that raise new types of Safety or effectiveness questions?

No. New models are of the same design construction as the models currently listed.

Q3. Does descriptive or Performance information demonstrate equivalence?

Yes. The product description and the intended use on the labeling and the Instruction for Use between the subject models and predicated models demonstrated the essential equivalence. The physical and performance characteristics evaluated in Table 2 in the Section 10 – Description of Modification to the device also showed the equivalence between the subject models and predicated models.

Conclusion:

As according to the decision path, the new models of Thermodilution Catheter can be submitted using substantial Equivalence.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

JUL - 1 2010

Biosensors International Pte., Ltd.
c/o Mr. Moses Tham
Director, Quality Assurance and Regulatory Affairs
21 Kallang Avenue #07-165/171
Singapore,
SINGAPORE 339412

Re: K101669
Trade/Device Name: Thermodilution Catheter and Accessories
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II (two)
Product Code: DQO
Dated: June 2, 2010
Received: June 14, 2010

Dear Mr. Tham:

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 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

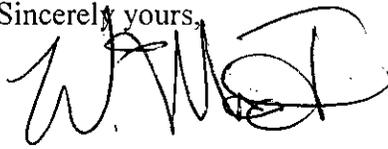
Page 2 – Mr. Moses Tham

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman

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): K101669

Device Name: THERMODILUTION CATHETER AND ACCESSORIES

Indications for Use:

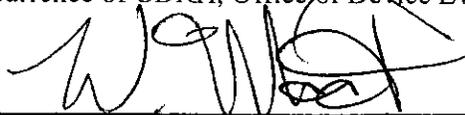
Biosensors flow-directed Thermodilution catheters are designed for use in critical care patients to measure cardiac output, right atrium, pulmonary artery and pulmonary capillary wedge pressures; continuously monitor pulmonary artery temperature, sample blood, intravenously administer drugs and solution and measure cardiac output via the cardiac output computers which interface with 14 kilo-ohms catheters. Different models are available for use in pediatric and adult patients.

The tips of the catheters are mounted with a latex balloon which, when inflated, protects the heart tissues from the product's tips during insertion; utilizes blood flow to direct the catheter tip through the right ventricle into the pulmonary artery.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101669