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

JAN - 5 2010

Revised on 2 December 2009

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 (K911710)

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.

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

Biosensors Thermodilution catheter product family included in 510K (K911710) is currently licensed for heparin-coated thermodilution catheter with PVC catheter tubing. This application involves the inclusion of additional models of Thermodilution Catheter where the catheter is designed with the non-coated PU catheter tubing.

Comparison was made for the above models against those that have already been licensed in K911710. 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 material type have been assessed and discussed further in Section 7 below.

7. Assessment of Performance Data used to justify Substantial Equivalence

Test Summary, *In-vitro*

Models with non-coated PU catheter tubing

Inclusion of the category of models is to provide an alternative to physician who prefers a different tautness of the catheter tubing.

Functionality performance tests were performed on the Thermodilution Catheter models with PU catheter tubing to evaluate the performance and integrity of the catheter in accordance to ISO 10555-1. Based on the test results which are of the acceptance criteria, the design construction of the catheter with PU tubing meets the ISO10555-1 standard.

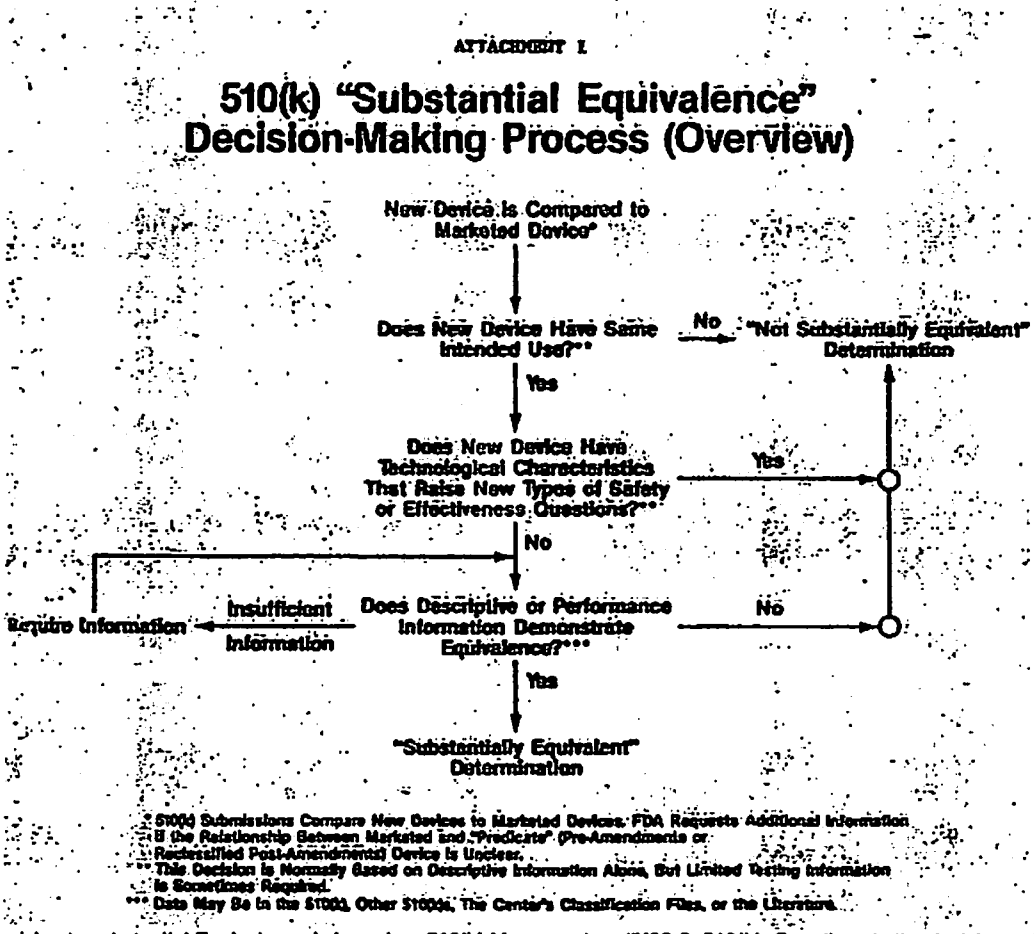
Test Summary, Biocompatibility

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 PU catheter tubing, is biocompatible and safe for its intended use.

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



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 to the Modification to the device also showed the equivalence subject models and predicated models.

Conclusion:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR 23 2010

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

Re: K083384
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: December 2, 2009
Received: December 7, 2009

Dear Mr. Tham:

This letter corrects our substantially equivalent letter of January 5, 2010.

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 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/ucm115809.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" (21CFR 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,

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): K083384

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 X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (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 K083384