K111050

APR 12 2012

5. 510(k) Summary

Date prepared: March 2, 2011

This 510(k) is being submitted by Anthony Beran on behalf of Starboard Medical, LLC.

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FDA Establishment Registration #: 3006845683

Contract Manufacturer:
Starboard Medical Jiangsu
Tel: 86-515-82306811
FDA Establishment Registration#: 3006845687

Trade Name:
The device trade name is Disposable Temperature probes/ sensors.

Device common, usual, or classification names:
Esophageal / Rectal temperature probe
Esophageal Stethoscope with temperature sensor

Classification:
Class II, product code BZT
Classification Panel: Anesthesiology, Reg# 21CFR 868.1920

Predicate Device:
The following devices have been identified as predicate devices:

SMITHS LEVEL 1 Esophageal / Rectal temperature probe – K863646
SMITHS LEVEL 1 Esophageal Stethoscope with temperature sensor – K854212

Description of device:
The Starboard Medical temperature probes are intended for use in clinical situations where continuous monitoring of patient's body temperatures is required. The probes are compatible with all monitoring instrumentation designed to accept YSI 400 series temperature probes or equivalent.

This 510(k) includes the following probes:

4009-ER (Esophageal / Rectal temperature probe – 9FR)
40012-ER (Esophageal / Rectal temperature probe – 12FR)
4009-ES (Esophageal Stethoscope with temperature sensor – 9FR)

40012-ES (Esophageal Stethoscope with temperature sensor – 12FR)
40018-ES (Esophageal Stethoscope with temperature sensor – 18FR)
40024-ES (Esophageal Stethoscope with temperature sensor – 24FR)
The probes are single use, and they are sterile.

Intended Use:
The Starboard Medical Esophageal / Rectal temperature probe is indicated for continuous patient temperature monitoring, when these placement sites are clinically recommended. The sensor is designed for insertion into the esophagus, nasopharynx, or rectum.
The Starboard Medical Esophageal Stethoscope with temperature sensor is indicated for continuous monitoring of patient temperature along with auscultation of the heart and lung sounds.

Technology Characteristics:
Both devices are substantially equivalent to the predicate devices based on material, technology, manufacturing processes, and performance.

Performance Data:
Both devices have been subjected to raw materials bio-compatibility testing, accuracy testing, and electrical testing and comparison.

Conclusion:
We believe the differences between the Starboard Medical devices and the predicate devices are minor, and conclude that the subject devices are as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Anthony Beran
President
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22845 Savi Ranch Parkway, Suite H
Yorda Linda, California 92887

APR 12 2012

Re: K111050
Trade/Device Name: Esophageal/ Rectal Temperature Probe, Catalog Numbers 4009-ER and 40012-ER. Esophageal Stethoscope with Temperature Sensor, Catalog Numbers 4009-ES, 40012-ES, 40018-ES, and 40024-ES.
Regulation Number: 21 CFR 868.1920
Regulation Name: Esophageal stethoscope with electrical conductors
Regulatory Class: II
Product Code: BZT
Dated: March 30, 2012
Received: April 5, 2012

Dear Mr. Beran:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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,

Anthony D. Watson

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Division of Anesthesiology, General Hospital,
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Center for Devices and
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Enclosure

4. Indications for Use Statement

510(k) Number (if known): Unknown.

Device Name(s):
Esophageal / Rectal Temperature Probe, Catalog Numbers 4009-ER and 40012-ER.
Esophageal Stethoscope with Temperature Sensor, Catalog Numbers 4009-ES, 40012-ES, 40018-ES, and 40024-ES.

Indications for Use:

Esophageal / Rectal temperature probe (4009-ER and 40012-ER):

The Starboard Medical Esophageal / Rectal temperature probe is indicated for continuous patient temperature monitoring, when these placement sites are clinically recommended. The probe is designed for insertion into the esophagus, nasopharynx, or rectum.

Esophageal Stethoscope with temperature sensor (4009-ES, 40012-ES, 40018-ES, and 40024-ES):

The Starboard Medical Esophageal Stethoscope with temperature sensor is indicated for continuous monitoring of patient temperature along with auscultation of the heart and lung sounds. The probe is designed for insertion into the esophagus.

Prescription Use: XXXX and/or Over-the-Counter Use: _____
(Part 21CFR801 Subpart D) (Part 21CFR801 Subpart C)

4/12/12
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111050