JUN 16 2014

510(k) Summary K140134

Date prepared: December 20, 2013

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

Contact:
Anthony Beran
President
Starboard Medical, LLC
22845-H Savi Ranch Parkway
Yorba Linda, CA 92887
Tel: 714 283 3099
Fax: 714 283 3033
Email: tony.beran@starboardmedical.com
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 Stethoscope with temperature sensor
Esophageal Stethoscope temperature sensor with attached earpiece
Esophageal/Rectal Temperature Probe

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

Predicate Device:
The following device has been identified as predicate devices:
Starboard Medical LLC. Esophageal Stethoscope with temperature sensor - K111050
Starboard Medical LLC. Esophageal/Rectal Temperature Probe - K111050

Description of device:
Esophageal Stethoscope has been used in clinical application for continuous measurement of temperature and auscultation of heart and lung sounds. Esophageal Stethoscope is used in anesthetized patients and is placed inside of esophagus.

The stethoscope consists of a sound transmitting part and a temperature monitoring part. Sound transmitting part consists of a PVC tube whose distal end has openings at the end and the side of the tube. The distal end is covered with a flexible membrane in form of a cuff. The proximal end of the tube has a Luer lock connector for the connection to the anesthesiologist monoscope with earpiece. Heart and lung sounds are transmitted across the esophageal wall and across the cuff membrane through distal openings into the PVC tube. The sound waves travel through the tube into the anesthesiologist monoscope and into the anesthesiologist's ear.

The temperature monitoring part consists of thermistor sub-assembly whose temperature sensing tip is placed inside of the PVC tube to the tube's distal end. On its proximal end, it terminates with an electrical connector for the connection to the patient monitoring system.

When in application, the sound transmitting part of the stethoscope is connected to a custom made connecting line with an earpiece or disposable monoscope. In many situations the anesthesiologist forgets the earpiece or monoscope so that the auscultations of the heart and lung sounds are not performed.

The proposed device incorporates the esophageal stethoscope and a monoscope in a single unit which would provide the anesthesiologist with an ease of application. The earpiece at the end of the connecting line is made of a memory ear plug. Prior to the insertion, the foam is squeezed and placed inside of the ear canal for auscultation of heart and lung sounds.

The Esophageal stethoscope with temperature sensor and Esophageal/Rectal temperature probe are non-sterile version of predicate device K111050.

This 510(k) includes the following probes:

4009-ESC (Esophageal Stethoscope temperature sensor with attached earpiece - 9FR sterile)
40012-ESC (Esophageal Stethoscope temperature sensor with attached earpiece - 12FR sterile)
40018-ESC (Esophageal Stethoscope temperature sensor with attached earpiece - 18FR sterile)
40024-ESC (Esophageal Stethoscope temperature sensor with attached earpiece - 24FR sterile)
NS4009-ESC (Esophageal Stethoscope temperature sensor with attached earpiece - 9FR non-sterile)
NS40012-ESC (Esophageal Stethoscope temperature sensor with attached earpiece -12FR non-sterile)
NS40018-ESC (Esophageal Stethoscope temperature sensor with attached earpiece - 18FR non-sterile)
NS40024-ESC (Esophageal Stethoscope temperature sensor with attached earpiece - 24FR non-sterile)
NS4009-ES (Esophageal Stethoscope with temperature sensor- 9FR non-sterile)
NS40012-ES (Esophageal Stethoscope with temperature sensor- 12FR non-sterile)
NS40018-ES (Esophageal Stethoscope with temperature sensor- 18FR non-sterile)
NS40024-ES (Esophageal Stethoscope with temperature sensor- 24FR non-sterile)
NS4009-ER (Esophageal/Rectal Temperature Probe-9FR NON-STERILE)
NS40012-ER (Esophageal/Rectal Temperature Probe-12FR NON-STERILE)

-The probes are single use.

Intended Use:
The Starboard Medical Esophageal Stethoscope temperature sensor with attached earpiece is indicated for continuous monitoring of patient temperature along with auscultation of the heart and lung sounds, and provides a direct connection to the anesthesiologist's ear

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 and provides for a connection to anesthesiologist monoscope which connects to the ear. The Starboard Medical Esophageal/Rectal Temperature probe is intended for continuous monitoring of patient's esophageal, rectal, and nasopharyngeal temperatures. The products are intended to be used as sterile and non-sterile.

Technology Characteristics:
This device is substantially equivalent to the predicate devices based on material, technology, manufacturing processes, and performance. The only difference is that the proposed device provides for direct connection to the anesthesiologist's ear.

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

Conclusion:
We believe the differences between the proposed device and the predicate devices are minor, and they are:

1. Catalog Numbers NS4009-ES to NS40024-ES are a non-sterile version of predicate device (K111050).
2. Catalog Numbers 4009ESC to 40024ESC and NS4009-ESC to NS40024-ESC incorporate the earpiece with connecting line to predicate device (K111050) in both sterile and non-sterile versions.
3. Catalog Numbers NS4009-ER and NS40012-ER are non-sterile version of predicate device (K111050).

In conclusion, the safety and effectiveness are not affected.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 16, 2014

Starboard Medical LLC
C/O Mr. Anthony Beran
President
22845 Savi Ranch Parkway, Suite H
Yorba Linda, California 92887

Re: K140134
Trade/Device Names: Esophageal Stethoscope with Attached Temperature Sensor
Clarisonus Plus Esophageal Stethoscope with Temperature Sensor
Esophageal/Rectal Temperature Probe

Regulation Number: 21 CFR 868.1920
Regulation Name: Stethoscope, esophageal, with electrical conductors
Regulatory Class: Class II
Product Code: BZT
Dated: May 9, 2014
Received: May 13, 2014

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Mary S. Runner -S

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K140134

Device Name
Esophageal Stethoscope with temperature sensor
Clarisonus Plus Esophageal Stethoscope with temperature sensor with attached earpiece
Esophageal/Rectal Temperature Probe

Indications for Use *(Describe)*

Indications for Use:

• The Clarisonus Plus Esophageal Stethoscope with temperature sensor with attached earpiece is intended for use when the esophageal temperature is continuously monitored along with the auscultation of the heart and lung sounds.
• The Esophageal Stethoscope with temperature sensor is intended for use when the esophageal temperature is continuously monitored along with the auscultation of the heart and lung sounds.
• The Esophageal/Rectal Temperature Probe is indicated for continuous monitoring of esophageal, rectal, and nasopharyngeal temperatures.

The products are intended for use in surgical and critical care patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman -S
Date: 2014.06.16 11:25:17 -04'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."