K081440

SEP 12 2008

SECTION 5: 510(k) Summary

I. Company Information

Smiths Medical ASD, Inc.
5700 West 23rd Avenue
Gary, IN 46406 USA

II. Contact Person:

Barbara Law
Regulatory Affairs Manager
Phone: (614)791-5568
Fax: (866)226-7156
Date prepared: May 20, 2008

III. Device Trade/Proprietary Name

Trade/Propriety Name:	Bivona® Adjustable and Fixed Neckflange Hyperflex™ Tracheostomy Tube Tracheostomy Tubes

IV. Device Classification Name

Classification Name:	Tracheostomy tube and tube cuff
Classification Code/Regulation:	JOH, 21 CFR 868.5800
Common/Usual Name:	Tracheostomy Tubes

V. Identification of Predicate Device

The Bivona® Adjustable and Fixed Neckflange Hyperflex™ Tracheostomy Tubes are identical to the Bivona® Adjustable and Fixed Neckflange Hyperflex™ Tracheostomy Tubes currently marketed by Smiths Medical. This modification consists of changes to the marketing claims and not the devices. Substantial equivalence and predicate device information is not applicable.

VI. Device Description

The Bivona® Adjustable and Fixed Neckflange Tracheostomy Tubes are sterile, single patient use, silicone tracheostomy tubes. They come in a variety of configurations for adults and pediatrics. They come cuffed (TTS®, Aire-Cuf® or Fome-Cuf®) or cuffless. The tubes are wire reinforced. Each tube is individually packaged in a peel-open tray with an obturator, decannulation cap, twill tape, and a disconnection wedge if appropriate. Additionally, a range of customizable options are offered allowing the clinician to create a tracheostomy tube to meet a specific patient's needs.

The purpose of this submission is to modify the indications for use for these devices to include the use of a properly placed Bivona® Adjustable and Fixed Neckflange Hyperflex™ Tracheostomy Tubes in the MRI environment. No changes have been made to the devices themselves.

VII. Indications for Use

The Bivona® Fixed Neckflange Hyperflex™ Tracheostomy Tube is intended to provide direct airway access for a tracheostomized patient up to 29 days. It may be reprocessed for single-patient use up to 10 times for adults sizes and up to 5 times for pediatric sizes.

The Bivona® Adjustable Neckflange Hyperflex™ Tracheostomy Tube is not intended for long term use. It is intended to provide temporary airway access for a

tracheostomized patient when determining the optimal tube length for a patient. It must be replaced with a fixed neck flange tracheostomy tube when the optimal length is determined.

The Bivona® Adjustable and Fixed Neckflange Hyperflex™ Tracheostomy Tubes with wire reinforcement have been determined to be MR–conditional. They may be used in a static magnetic field of 3–Tesla or less with spatial gradient magnetic field of 720–Gauss/cm or less and maximum MR system reported whole-body averaged specific absorption rate (SAR) of 3-W/Kg for 15 minutes of scanning. Special care should be taken as follows:

(1) Ensure that the tracheostomy tube is firmly secured using the tracheostomy tube holder supplied or equivalent commercially available fixation device in order to prevent movement in the MRI environment.
(2) Ensure that the inflation valve is securely taped down in order to prevent its movement in the MRI environment.
(3) MR image quality may be compromised if the area of interest is close to the position of the tube and/or inflation valve. The inflation valve should be secured away from the area of interest. Optimization of MR imaging parameters to compensate for the presence of this device may be necessary.
(4) A temperature rise of less than or equal to 0.4°C was noted at a maximum MR system-reported whole body averaged specific absorption rate (SAR) of 3-W/kg for 15-minutes of MR scanning in a 3-Tesla MR system using a transmit/receive body coil.

The Bivona® Adjustable and Fixed Neckflange Hyperflex™ Tracheostomy Tubes are contraindicated for use with lasers or electrosurgical devices where their output may contact and damage the tube. The Bivona® Adjustable Neckflange Hyperflex™ Tracheostomy Tube is contraindicated for use in home care settings.

VIII. Technological Characteristics

There are no changes to the Bivona® Adjustable and Fixed Neckflange Tracheostomy Tubes. The intention of this submission is to modify the marketing claims to include the use of these products in an MRI environment.

IX. Non-Clinical Data

Bench testing confirms that the Bivona® Adjustable and Fixed Neckflange Tracheostomy Tubes with wire reinforcement have been determined to be MR–conditional under the following conditions: a static magnetic field of 3–Tesla or less with spatial gradient magnetic field of 720–Gauss/cm or less and maximum MR system reported whole-body averaged specific absorption rate (SAR) of 3-W/Kg for 15 minutes of scanning.

X. Clinical Data

Not required.

XI. Conclusion

Bench testing confirms that the Bivona® Adjustable and Fixed Neckflange Tracheostomy Tubes with wire reinforcement have been determined to be MR–conditional.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 2 2008

Ms. Barbara Law
Regulatory Affairs Manager
Smiths Medical ASD, Incorporated
6250 Shier Rings Road
Dublin, Ohio 43016

Re: K081440
Trade/Device Name: Bivona® Adjustable and Fixed Neckflange Hyperflex™ Tracheostomy Tubes
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: JOH
Dated: August 22, 2008
Received: September 9, 2008

Dear Ms. Law:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: Bivona® Adjustable and Fixed Neckflange Hyperflex™ Tracheostomy Tubes

Indications for Use:

The Bivona® Fixed Neckflange Hyperflex™ Tracheostomy Tube is intended to provide direct airway access for a tracheostomized patient up to 29 days. It may be reprocessed for single-patient use up to 10 times for adults sizes and up to 5 times for pediatric sizes.

The Bivona® Adjustable Neckflange Hyperflex™ Tracheostomy Tube is not intended for long term use. It is intended to provide temporary airway access for a tracheostomized patient when determining the optimal tube length for a patient. It must be replaced with a fixed neck flange tracheostomy tube when the optimal length is determined.

The Bivona® Adjustable and Fixed Neckflange Hyperflex™ Tracheostomy Tubes with wire reinforcement have been determined to be MR–conditional. They may be used in a static magnetic field of 3–Tesla or less with spatial gradient magnetic field of 720–Gauss/cm or less and maximum MR system reported whole-body averaged specific absorption rate (SAR) of 3-W/Kg for 15 minutes of scanning.

The Bivona® Adjustable and Fixed Neckflange Hyperflex™ Tracheostomy Tubes are contraindicated for use with lasers or electrosurgical devices where their output may contact and damage the tube. The Bivona® Adjustable Neckflange Hyperflex™ Tracheostomy Tube is contraindicated for use in home care settings.

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

for MTT

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

510(k) Number: K081440