

SECTION 5: 510(k) Summary

FEB 23 2009

- I. Company Information**
Smiths Medical ASD, Inc.
5700 West 23rd Avenue
Gary, IN 46406 USA
- II. Contact Person:**
Timothy J. Talcott
Director, Regulatory Affairs and Compliance
Phone: (603)352-3812, ext. 2457
Fax: (603)355-8157
- III. Device Trade/Proprietary Name**
Trade/Propriety Name: Bivona® 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® Tracheostomy Tubes are identical to the Bivona® Tracheostomy Tubes currently marketed by Smiths Medical. This modification consists of changes to the marketing claims and not the devices. The Bivona® Fixed and Adjustable Neckflange Hyperflex™ Tracheostomy Tubes were found to be MR-Conditional under 510K K081440.
- VI. Device Description**
The Bivona® Tracheostomy Tubes are sterile, single patient use, silicone tracheostomy tubes. They come in a variety of configurations for adults, pediatric and neonatal patients. They come cuffed (TTS®, Aire-Cuf® or Fome-Cuf®) or cuffless. The tubes may be wire reinforced or plain silicone. 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 include the use of properly placed Bivona® Tracheostomy Tubes in the MRI environment. No changes have been made to the devices themselves.
- VII. Indications for Use**
The Bivona® 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.
- VIII. Technological Characteristics**
There are no changes to the Bivona® 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® cuffless and Fome-Cuf Tracheostomy Tubes with wire reinforcement and Bivona® cuffed Tracheostomy Tubes (Aire-Cuf® or TTS®) with or without wire reinforcement have been determined to be MR-Conditional according to ASTM F2503-05 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.

The Bivona® cuffless or Fome-Cuf® Tracheostomy Tubes without wire reinforcement have been determined to be MR-Safe according to ASTM F2503-05 based on the nature of the materials of construction. They contain no metal.

X. Clinical Data

Not required.

XI. Conclusion

Bench testing confirms that the Bivona® cuffless and Fome-Cuf Tracheostomy Tubes with wire reinforcement and Bivona® cuffed Tracheostomy Tubes (Aire-Cuf® or TTS®) with or without wire reinforcement have been determined to be MR-Conditional according to ASTM F2503-05 and the Bivona® cuffless or Fome-Cuf® Tracheostomy Tubes without wire reinforcement have been determined to be MR-Safe according to ASTM F2503-05.

SMITHS MEDICAL ASD, INC.



Timothy J. Talcott
Director, Regulatory Affairs and Compliance



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 2009

Mr. Daniel Coates
Senior, Design Engineer
Smith's Medical ASD, Incorporated
5700 West 23rd Avenue
Gary, Indiana 46406

Re: K083641
Trade/Device Name: Bivona® Tracheostomy Tubes
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: JOH
Dated: February 16, 2009
Received: February 17, 2009

Dear Mr. Coates:

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.

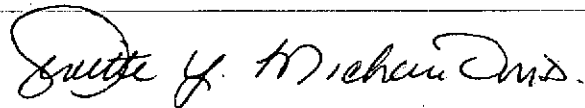
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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,



Ginette Y. Michaud, M.D.

Acting 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): K083641

Device Name: Bivona® Tracheostomy Tubes

Indications for Use:

The Bivona® 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.

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)

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(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083641