PC Technology: Biocompatible coating for medical device with reduction in biofilm formation – FDA label claim –

K000801

JUN 1 9 2000

510(k) Summary of Safety and Effectiveness

Trade Name: Fluoroplastic Ventilation Tubes
Common Name: Tympanostomy Tubes
Classification Name: Tympanostomy Tubes (CFR 21 § 874.3880)

Official Contact: Alicia E. Farage
Senior Regulatory Affairs Specialist
Smith & Nephew, Inc., ENT Division
2925 Appling Road
Bartlett, TN 38133
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Date Prepared: June 12, 2000

The PC Coated Fluoroplastic Ventilation Tubes are substantially equivalent to the current fluoroplastic tubes marketed by Smith & Nephew, Inc., ENT Division, and the fluoroplastic tubes marketed by Xomed.

Intended Use
All of these fluoroplastic ventilation tubes have the same primary intended use: ventilate the middle ear subsequent to otitis media.

Material of Tubes
Fluoroplastic tubes from Smith & Nephew, Inc. are currently manufactured from fluoroplastic meeting ASTM F 754 as are the Xomed Activent® Tubes.

Design Features
Various designs of both tubes are available to meet physician preference.

	PC Coated Fluoroplastic Vent Tubes (Smith & Nephew, Inc., ENT Division)	Current Fluoroplastic Vent Tubes (Smith & Nephew, Inc., ENT Division)	Fluoroplastic Vent Tubes (Medtronic Xomed Surgical Products, Inc.)
Intended Use	Ventilation of middles ear subsequent to Otitis Media	Ventilation of middles ear subsequent to Otitis Media	Ventilation of middles ear subsequent to Otitis Media
Material	Fluoroplastic/PC Coating	Fluoroplastic	Fluoroplastic/Silver oxide-impregnated
Coating Characteristics	Resists Bacterial Adhesion	N/A	Bacteriostatic
How Shipped	Supplied Sterile	Supplied Sterile	Supplied Sterile

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PC COATING TESTING INFORMATION

The coating has been shown to be resistant to staphylococcal biofilm formation and pseudomonal biofirm formation. Six month soak testing (agitated bath of saline at 37 degrees Celsius) indicated that the coating remains in place. Three month ISO 10993-1 biocompatibility testing indicates no reaction.

Differences between these PC Coated Fluoroplastic Ventilation Tubes and the predicate devices should not affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 9 2000

Ms. Alicia E. Farange
Senior Regulatory Affairs Specialist
Smith & Nephew, Inc.
2925 Appling Road
Bartlett, TN 38133

Re: K000801
Trade Name: Fluoroplastic Ventilation Tubes
Regulatory Class: II
CFR: 874.3880
Product Code: 77ETD
Dated: May 26, 2000
Received: May 31, 2000

Dear Ms. Farage:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K000801

510(k) Number:
Device Name: PC Coated Fluoroplastic Ventilation Tubes

Indications for Use:

- Chronic otitis media with effusion (serous, mucoid, or purulent)
- Recurrent episodes of acute otitis media despite conventional medical treatment
- A record of persistent high negative middle ear pressure associated with one or more of the following system:
  1. Conductive hearing loss that is symptomatic
  2. Persistent or recurrent otalgia
  3. Persistent or recurrent vertigo, tinnitus, or both
- Retraction pocket of the tympanic membrane

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K000801