

K062385

SEP 27 2006

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
Grace Medical Adjustable Length and Fixed Length Partial and Total Ossicular Replacement Prostheses

Trade Name: Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes

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

Official Contact: Jeff Cobb
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Date Prepared: August 14, 2006

Predicate Devices – The Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes are substantially equivalent to the predicate devices listed below.

<u>Predicate Device</u>	<u>Manufacturer</u>	<u>510(k) Number (if known)</u>
Fluoroplastic Ventilation Tubes	Gyrus ENT	K992222
Tympanostomy Tubes	Grace Medical Inc.	K943325

Intended Use – The Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes have the same primary intended use as the predicate devices which consist of:

- 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
- Atelectasis resultant from retraction pocket of the tympanic membrane or eustachian tube dysfunction.

Materials – The Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes are manufactured from the same materials as the Gyrus ENT Fluoroplastic Ventilation Tubes.

Design Features – Various designs of Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes are available to meet physician preference. The design features of the Grace Medical PTFE Ventilation Tubes should not raise new safety or effectiveness issues.

Comparison Charts

	GRACE MEDICAL BLUE PTFE (FLUOROPLASTIC) VENTILATION TUBES	GRACE MEDICAL VENTILATION TUBES (K943325)	GYRUS ENT FLUOROPLASTIC VENTILATION TUBES (K992222)
Intended Use	<ul style="list-style-type: none"> • 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: <ol style="list-style-type: none"> 1. Conductive hearing loss that is symptomatic 2. Persistent or recurrent otalgia 3. Persistent or recurrent vertigo, tinnitus, or both • Atelectasis resultant from retraction pocket of the tympanic membrane or eustachian tube dysfunction. 	Same	Same
Primary Material(s)	Blue (PTFE) Fluoroplastic (Same as Gyrus ENT)	Fluoroplastic	Blue (PTFE) Fluoroplastic
How Supplied	Sterile	Sterile	Sterile

Differences between the Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes and the predicate devices should not raise new issues regarding safety or effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Grace Medical, Inc.
c/o Jeff Cobb
Vice President
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8500 Wolf Lake Drive, Suite 110
Memphis, TN 38133

SEP 27 2006

Re: K062385

Trade/Device Name: Grace Medical Blue PTFE (Fluoroplastic) Ventilation Tubes
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy tube
Regulatory Class: Class II
Product Code: ETD
Dated: August 14, 2006
Received: August 15, 2006

Dear Mr. Cobb:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear, Nose
and Throat Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

510(k) Number: K062385

Device Name: Blue PTFE (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
- Atelectasis resultant from retraction pocket of the tympanic membrane or eustachian tube dysfunction.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format I-2/96)



(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K062385