

K062672

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
 GRACE MEDICAL PC COATED TYMPANOSTOMY TUBES**

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

OCT 24 2006

Official Contact: Jeff Cobb

Grace Medical, Inc.
 8500 Wolf Lake Drive, Suite 110
 Memphis, TN 38133

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 Date Prepared: September 8, 2006

Predicate Devices – The Grace Medical PC Coated Tympanostomy Tubes are substantially equivalent to the current silicone tympanostomy tubes marketed by Grace Medical, Inc. (K943325 & K981575) and PC Coated Tympanostomy Tubes (Pacific™) (K000801) marketed by Gyrus ENT.

Intended Use – The Grace Medical PC Coated Tympanostomy Tubes have the same primary intended use as the predicate devices – A device that is intended to be implanted for ventilation or drainage of the middle ear.

1) Indications for Use

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

Material of Tubes – The Grace Medical PC Coated Tympanostomy Tubes are manufactured from medical grade silicone. Each tube is coated with a layer of PC1036 phosphorylcholine.

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

	PC Coated Tympanostomy Tubes (Grace Medical)	Uncoated Tympanostomy Tubes (Grace Medical)	PC Coated Tympanostomy Tubes (Gyrus ENT)	Uncoated Tympanostomy Tubes (Gyrus ENT)
Intended Use	Ventilation & Drainage of Middle Ear	Ventilation & Drainage of Middle Ear	Ventilation & Drainage of Middle Ear	Ventilation & Drainage of Middle Ear
Material	Silicone w/ PC1036 Coating	Fluoroplastic, Titanium, & Silicone	Fluoroplastic/PC1036 Coating	Fluoroplastic
Coating Characteristics	Resists Biofilm Formation ¹	N/A	Resists Biofilm Formation ¹	N/A
How Shipped	Supplied Sterile	Supplied Sterile	Supplied Sterile	Supplied Sterile

PC1036 Coating Information – The PC1036 coating has been shown to be resistant to staphylococcal biofilm formation and pseudomonal biofilm formation.¹

Differences between the Grace Medical PC Coated Tympanostomy Tubes and the predicate devices should not affect the safety or effectiveness.

¹ Berry JA, et al.: *In vitro resistance to bacterial biofilm formation on coated fluoroplastic tympanostomy tubes*. Otolaryngology Head and Neck Surgery. 2000 Sep;123(3):246-51.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

OCT 24 2006

Re: K062672

Trade/Device Name: Grace Medical PC Coated tympanostomy Tubes
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy tube
Regulatory Class: Class II
Product Code: ETD
Dated: September 7, 2006
Received: September 26, 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.

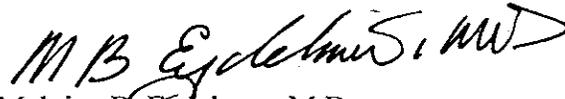
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 – Mr. Jeff Cobb

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

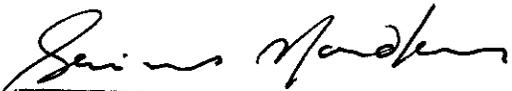
510(k) Number:
Device Name: PC Coated Tympanostomy Tubes

1) Indications for Use

- (a) Chronic otitis media with effusion (serous, mucoid, or purulent).
- (b) Recurrent episodes of acute otitis media despite conventional medical treatment.
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 - (ii) Persistent or recurrent otalgia.
 - (iii) Persistent or recurrent vertigo, tinnitus, or both.
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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)	X	OR	Over-The-Counter Use (Optional Format 1-2/96)
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(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

Prescription Use X
(Per 21 CFR 801.109)

510(k) Number K062672