DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 1998

Anthony D. Prescott
Grace Medical, Inc.
31 Highway 70
Suite 107
Bartlett, TN 38133

Re: K981575
Tympanostomy Tube (see enclosure)
Dated: April 30, 1998
Received: May 4, 1998
Regulatory class: II
21 CFR 874.3880/Procode: 77 ETD

Dear Mr. Prescott:

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) 594-4613. 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" (21 CFR 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ENCLOSURE

Grace Catalog #	Description	510(k) page	Inner Diameter
1	Goode T-Tube	21	1.14
2	Goode T-Tube	21	1.32
3	Butterfly Vent Tube	23	1.27
4	Goode T-Grommet Vent Tube	25	1.25
5	Cohen T-Grommet Vent Tube	26	1.25
6	Baxter T-Grommet Vent Tube	27	1.25
7	Paparella Type Vent Tube	29	1.02
8	Paparella Type Vent Tube	29	1.27
9	Paparella Type Vent Tube	29	2.03
10	Per-Lee Vent Tube	30	1.57
11	Donaldson Vent Tube	32	1.14
12	Armstrong Beveled Grommet Vent Tube	34	1.14
13	Armstrong Beveled Vent Tube	35	1.14
14	Parasol/Umbrella Vent Tube	37	1.02
15	Parasol/Umbrella Vent Tube	37	1.52
16	Parasol/Umbrella Vent Tube	37	2.03
17	Shepard Grommet Vent Tube	38	1.14
18	Baxter Beveled Vent Tube	40	1.27
19	Baxter Beveled Vent Tube	40	0.97

510(k) Number (if known): K981575

Device Name: Tympanostomy Tube

Indications For Use:

Indications for insertion of a tympanostomy tube into an incision in the tympanic membrane include any of the following:

- Chronic otitis media with effusion characterized as either serous, mucoid, or purulent
- Recurrent acute otitis media which fails to respond satisfactorily to alternative therapies
- A patient with a history of persistent high negative middle ear pressure which may be associated with conductive hearing loss that is symptomatic, persistant or recurrent otalgia, persistent or recurrent vertigo and/or tinnitus
- 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)

Perscription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

David A. Seyton

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981575