November 24, 2023

Grace Medical, Inc.
Mark Melton
VP of Quality Assurance & Regulatory Affairs
8500 Wolf Lake Drive, Suite 110
Memphis, Tennessee 38133

Re: K232059
Trade/Device Name: Tympanostomy Tube
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy Tube
Regulatory Class: Class II
Product Code: ETD
Dated: October 26, 2023
Received: October 26, 2023

Dear Mark Melton:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232059

Device Name
Tympanostomy Tube

Indications for Use *(Describe)*

1) Chronic otitis media with effusion characterize as either serous, mucoid, or purulent.
2) Recurrent acute otitis media which fails to respond satisfactorily to alternative therapies.
3) A patient with a history of persistent high negative middle ear pressure which may be associated with conductive hearing loss that is symptomatic, persistent or recurrent otalgia, persistent or recurrent vertigo and/or tinnitus.
4) Atelectasis recurrent form retraction pocket of the tympanic membrane or eustachian tube dysfunction.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

SUBMITTER:	Grace Medical Inc. 8500 Wolf Lake Drive, Suite 110 Memphis, TN 38133 Phone: 901-386-0990
CONTACT PERSON:	Mark Melton VP of Regulatory Affairs and Quality Assurance mark.melton@gracemedical.com.com

510(k) Number:	K232059
DATE PREPARED:	November 24, 2023
COMMON NAME:	ETFE Tympanostomy Tube
PROPRIETARY NAME:	Tympanostomy Tube
PREDICATE DEVICES:	Grace Medical, Inc. PTFE Tympanostomy Tube (K062385) and Micromedic, Inc. ETFE Tympanostomy Tube (K830228)
CLASSIFICATION NAME:	21 CFR § 874.3880
PRODUCT CODES:	ETD
DEVICE CLASS:	Class II
MATERIAL:	ETFE Fluoroplastic

DEVICE DESCRIPTION:

The Grace Medical, Inc. ETFE (Fluoroplastic) Ventilation Tubes are intended to ventilate the middle ear subsequent to otitis media. The placement of the tubes in the tympanic membrane provides the means for any fluid buildup in the middle ear while creating an avenue of the passage of air to equalize pressure on either side of the drum. These ventilation tubes will be made from ETFE (fluoroplastic). ETFE has been used as a material for ventilation tubes and other middle ear application for many years.

- The Grace Medical, Inc. PTFE ventilation tubes were cleared via 510(k) No. K062385.
- The difference in this new submission as that of K062385 is the material.
- Micromedics, Inc. ETFE ventilation tubes manufactured from the same materials were cleared via 510(k) No. K830228.

These ETFE ventilation will be manufactured by Stamm AG the same company that manufactures ETFE tubes that are already available on the US market.

INDICATIONS FOR USE:

1. Chronic otitis media with infusion characterized as either serous, mucoid, or purulent.
2. Recurrent acute otitis media which fails to respond satisfactorily to alternative therapies.
3. A patient with a history of persistent high negative middle ear pressure which may be associated with conductive hearing loss that is symptomatic, persistent or recurrent otalgia, persistent or recurring vertigo and/or tinnitus.
4. Atelectasis resultant from retraction pocket of tympanic membrane or eustachian tube dysfunction.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

The Grace Medical, Inc. ETFE tubes are the same dimensionally and the intended use as the primary predicate PTFE tube. The Grace Medical, Inc. ETFE tubes are the same as the secondary predicate tube design, materials, intended use, and manufacturing processes. The Grace Medical, Inc. ETFE tubes surgical technique are the same as the predicates. In addition, the Instruction for use is the same as its predicates in this submission.

Parameter	Grace Medical, Inc. ETFE Fluorplastic (K232059)	PRIMARY PREDICATE Grace Medical, Inc. PTFE Fluorplastic (K062385)	SECONDARY PREDICATE Micromedic, Inc. ETFE Fluoroplastic (K830228)	Comparison
General Description	Tympanostomy Tube	Tympanostomy Tube	Tympanostomy Tube	Same
Indications for Use	Indicated where chronic Eustachian tube dysfunction does not respond the conventional therapy.	Indicated where chronic Eustachian tube dysfunction does not respond the conventional therapy.	Indicated where chronic Eustachian tube dysfunction does not respond the conventional therapy.	Same
Intended Use	Indicated where chronic Eustachian tube dysfunction does not respond the conventional therapy.	Indicated where chronic Eustachian tube dysfunction does not respond the conventional therapy.	Indicated where chronic Eustachian tube dysfunction does not respond the conventional therapy.	Same
Design	ETFE Ventilation Tube	PTFE Ventilation Tube	ETFE Ventilation Tube	Similar
Technological Characteristics	Vent Tube to be placed in the tympanic membrane to allow air ventilation and fluid drainage	Vent Tube to be placed in the tympanic membrane to allow air ventilation and fluid drainage	Vent Tube to be placed in the tympanic membrane to allow air ventilation and fluid drainage	Same
Dimensional	Same as Grace Medical PTFE	Same a Grace Medical ETFE	Negligible to Grace Medical	Similar
Material	ETFE Fluoroplastic	PTFE Fluoroplastic	ETFE Fluoroplastic	Similar
Sterile	EO	EO	EO	Same

SUMMARY OF NON-CLINAL TESTS SUBMITTED:

Bench Testing:

No testing was provided in the original Grace Medical PTFE (K062385) submission. Testing was provided for the subject device to support substantial equivalence, but it did not follow any ASTM standard. Performance testing was completed to demonstrate the characteristics of the two materials of the subject (ETFE) vs. primary predicate (PTFE) devices. Non-clinical bench compression testing was conducted on Grace Medical, Inc. ETFE and PTFE material to only show that ETFE is a tougher material than the PTFE of the same design that is currently FDA 510(k)

approved (K062385). Grace medical did not perform compression testing on the secondary predicate device (K830228) tube because it has the same dimensions and material type as the subject device.

Biocompatibility:

The subject device is a permanent implant, the following endpoints were assessed according to ISO 10993-1 and US FDA guidance document "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process'" (2023):

- Cytotoxicity
- Sensitization
- Irritation
- Material mediated pyrogenicity
- Implantation
- Acute, subacute, sub-chronic, and chronic systemic toxicity
- Genotoxicity
- Carcinogenicity

The following guidance and standard documents were used in the biological evaluation:

- US FDA guidance document "*Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process'*" (2023)
- CDRH Learn FDA Webinar: Color Additives For Medical Devices (February 2016)
- US FDA guidance document "The Least Burdensome Provisions: Concept and Principles (2019)
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 05 April 2017 on Medical Devices
- ISO 10993-1:2018 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
- ISO 10993-2:2022 *Biological evaluation of medical devices – Part 2: Animal welfare and requirements*
- ISO 10993-5:2009 *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
- ISO 10993-12:2021 *Biological evaluation of medical devices – Part 12: Sample preparation and reference materials*
- ISO 10993-17:2002 *Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances*
- ISO 10993-18:2020/Amd1:2022 *Biological evaluations of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process*
- ISO 10993-23:2021 *Biological evaluation of medical devices – Part 23: Tests for irritation*

- ISO/TS 21726:2019 *Biological evaluation of medical devices — Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents*
- Endotoxin evaluation – ANSI AAMI ST72:2019; Bacterial Endotoxin test on Methods, routine monitoring, and alternatives to batch testing - Limulus amebocyte lysate (LAL) test.

The following guidance and standard documents were used in the Sterility evaluation:

- EN 556-1:2001 – Sterilization of medical devices. Requirements for medical devices to be designated "STERILE" – Part 1. Requirements for terminally sterilized medical devices
- EN ISO 11135:2014 – Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices
- EN ISO 11138-1:2017 – Sterilization of health care products -- Biological indicators -- Part 1: General requirements
- EN ISO 11138-2:2017 – Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes
- EN ISO 11737-1:2018 – Sterilization of health care products— Microbiological methods— Part 1: Determination of the population of microorganisms on product
- EN ISO 11737-2:2009 – Sterilization of health care products— Microbiological methods— Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ISO 10993-7:2008/Amd 1:2019 – Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
- AAMI TIR 28-2016 – Product adoption and process equivalence for ethylene oxide sterilization
- ISO 11607-1; Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2; Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

The following guidance and standard documents were used in the Ship Testing:

- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- FedEx ISTA 6A – FedEx Ship Test Guidelines

The following guidance and standard documents were used in Packaging Testing:

- ASTM F1886/F1886M; Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F3039-15; Standard Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration

SUBSTANTIAL EQUIVALENCE CONCLUSION:

The Grace Medical, Inc. ETFE tubes in this submission is the same as the primary predicate (K062385) and (K830228) in regards to implant design, intended use, and surgical technique.

Grace Medical Inc. has determined that the material change for the ETFE Tympanostomy Tubes do not alter the system function, strength and stability in regards to its intended use. Therefore, the Grace Medical, Inc. ETFE Tympanostomy Tubes are substantially equivalent to the predicate devices, and do not raise different questions of safety or effectiveness.

- Indication for use are equivalent.
- Material strength is similar.
- Methods of sterilization are the same.
- Intended use is the same.
- Designs are the same.