August 18, 2026

Grace Medical, Inc.
Thomas Fearnley
Regulatory Affairs Manager
8500 Wolf Lake Drive
Suite 110
Memphis, TN 38133

Re: K260266
Trade/Device Name: Tympendi™ (810)
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, Nose, And Throat Synthetic Polymer Material
Regulatory Class: Class II
Product Code: KHJ
Dated: July 17, 2026
Received: July 17, 2026

Dear Thomas Fearnley:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

JOYCE C. LIN -S

for 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260266

Please provide the device trade name(s).

Tympendi™ (810)

Please provide your Indications for Use below.

Tympendi™ is designed to temporarily cover the tympanic membrane after surgical procedures in the middle ear and is not intended for use beyond twenty-one (21) days.
Tympendi™ serves as a physical barrier to protect the TM and underlying structures. It reduces the risk of adhesion between the TM and packing materials.

Please select the types of uses (select one or both, as applicable).

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

510(k) #: K260266

510(k) Summary

Prepared on: 2026-08-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Grace Medical, Inc.
Applicant Address	8500 Wolf Lake Drive Suite 110 Memphis TN 38133 United States
Applicant Contact Telephone	(901)386-0990
Applicant Contact	Mr. Thomas Fearnley
Applicant Contact Email	thomas.fearnley@gracemedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Tympendi™ (810)
Common Name	Ear, nose, and throat synthetic polymer material
Classification Name	Polymer, Ent Synthetic-Polyamide (Mesh Or Foil Material)
Regulation Number	874.3620
Product Code(s)	KHJ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K033796	KURZ Silicone Strips	KHJ

Device Description Summary

21 CFR 807.92(a)(4)

The Tympendi™ is a sterile, single-use silicone covering designed for temporary placement over the tympanic membrane (TM) following middle ear surgical procedures. The device serves as a physical barrier to protect the TM and underlying structures, reducing the risk of adhesion of surgical packing or other materials to the membrane during the healing process. The device is not intended for use beyond 21 days.

The Tympendi™ is manufactured from medical-grade, biocompatible silicone elastomer. The material is clear, flexible, and conformable to the surface of the tympanic membrane, allowing for easy visualization of the underlying tissue. The device is a conical shaped disc with a center tab.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Tympendi™ is designed to temporarily cover the tympanic membrane after surgical procedures in the middle ear and is not intended for use beyond twenty-one (21) days.
Tympendi™ serves as a physical barrier to protect the TM and underlying structures. It reduces the risk of adhesion between the TM and packing materials.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use for the Tympendi™ are the same as the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The Tympendi™ is substantially equivalent to the predicate device with respect to technological characteristics. The subject device is manufactured from the same material as the predicate device, silicone. The Tympendi™ is provided in a disc configuration, whereas the predicate device is provided in strip form.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Simulated use testing to assess flexibility, tensile strength and tear resistance, elongation at break, adhesion (peel) testing, and surface characterization via scanning electron microscopy (SEM) was performed, with the reference device, K970910 (Medtronic Silicone Sheet) as a comparator. Clinically relevant acceptance criteria have been established for each test. Biocompatibility testing was leveraged from the reference device, K981575 (Grace Medical Tympanostomy Tube).

No additional clinical testing was provided in this submission in order to demonstrate substantial equivalence.

Performance testing data on the device met the clinically relevant acceptance criteria based on the specific performance needs for the proposed intended use. Therefore the device does not raise any new concerns of safety and effectiveness as compared to the predicate.