



April 23, 2026

Tusker Medical, Inc.
Nan McIntosh
Sr. Regulatory Affairs Specialist
7000 W. William Cannon Dr. Suite 110
Austin, Texas 78735

Re: K252436

Trade/Device Name: Tula Tympanostomy Tube Delivery Device
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy Tube
Regulatory Class: Class II
Product Code: ETD
Dated: March 26, 2026
Received: March 27, 2026

Dear Nan McIntosh:

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

510(k) Number (if known)

K252436

Device Name

Tula Tympanostomy Tube Delivery Device

Indications for Use (Describe)

The Tula Tympanostomy Tube Delivery Device is intended to deliver a tympanostomy tube (also referred to as a ventilation tube) through the tympanic membrane of the patient and is indicated to be used in office or operating room settings for pediatric (aged 6 months and older) and adult patients.

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.

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510(k) Summary According to 21 CFR 807.92

Date Prepared: April 22nd, 2026

Submitter Name & Address: Tusker Medical, Inc.
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Austin, TX 78735

FDA Establishment Owner/Operator Number: 1020279

FDA Establishment Registration Number: 3012130335

Submitter / Primary Contact: Nan McIntosh
Sr. Regulatory Affairs Specialist
(909) 306-9393
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Device Trade / Proprietary Name: Tula^o Tympanostomy Tube Delivery Device

Device Common Name: Tympanostomy Tube Inserter with pre-loaded ventilation tube

Device Classification Name: Tube, Tympanostomy

Regulation Medical Specialty: Ear Nose & Throat

Review Panel(s): Ear Nose & Throat

Product Code(s): ETD

Regulation Numbers: 21 CFR 874.3880

Submission Type: Traditional 510(k)

Device Class: Class II

Predicate Device: Hummingbird Tympanostomy Tube System (K221254)

Reference Device: TULA Tube Delivery System (K171239)

Device Description:

The Tula Tympanostomy Tube Delivery Device (TDD) provides a means to create a myringotomy through which a tympanostomy tube is placed by single button-controlled activation. Once the button is pushed, the TDD executes a series of automated actions in rapid fashion, creating the myringotomy and delivering the tube in less than 500 msec. The cutting component of the TDD is recessed within the device and is only briefly exposed

upon TDD actuation. The cutting component extends no more than 3 mm from the distal edge of the device and immediately retracts back into the device.

The TDD is a single patient-use device that is provided sterile and non-pyrogenic, through a sterilization process using ethylene oxide gas.

Intended Use:

The TDD is intended to deliver a tympanostomy tube through the tympanic membrane (TM) of the patient. It combines the separate functions of creating a myringotomy, positioning and placing a ventilation tube across the TM.

Indications for Use:

The Tula Tympanostomy Tube Delivery Device is intended to deliver a tympanostomy tube (also referred to as a ventilation tube) through the tympanic membrane of the patient and is indicated to be used in office or operating room settings for pediatric (aged 6 months and older) and adult patients.

Summary of Technological Characteristics Compared to Predicate Device:

Parameter	TDD Subject Device	HTTS Predicate Device	TDS Reference Device	Comment
Trade name	Tula Tympanostomy Tube Delivery Device (TDD)	Hummingbird Tympanostomy Tube System (HTTS)	Tula Tube Delivery System (TDS)	None
510(k) Number	K252436	K221254	K171239	None
Class	II	Same	Same	No difference
Product Code	ETD	Same	Same	No difference
Indications for Use	The Tula Tympanostomy Tube Delivery Device (TDD) is intended to deliver a tympanostomy tube (also referred to as a ventilation tube) through the tympanic membrane of the patient and is indicated to be used in office or operating room for pediatric (aged 6 months and older) and adult patients.	The Hummingbird Tympanostomy Tube System (HTTS) is intended to deliver a tympanostomy tube (also referred to as a ventilation tube) through the tympanic membrane of the patient and is indicated to be used in office settings for pediatric patients 6 months and older.	The Tula Tube Delivery System is intended to provide a means to create a myringotomy with insertion of a preloaded Grommet type tympanostomy tube.	The subject device expands the indication for use to include use in the operating room and treatment of adult patients compared to the predicate device.
Target Population	Pediatric (aged 6 months and older) and adult patients	Pediatric patients 6 months and older	Adults and Children	The subject device includes adult patients in addition to the pediatric population when compared to the predicate device.
Technological Characteristics				
Technology Description	Single use handheld device comprised of a stainless steel shaft and a	Same	Same	No difference

Parameter	TDD Subject Device	HTTS Predicate Device	TDS Reference Device	Comment
	plastic handle which can create a myringotomy and place a preloaded tympanostomy tube across a tympanic membrane.			
Pre-loaded Tube	Yes	Same	Same	No difference
Principals of Operation	Following local/general anesthesia, a myringotomy is created using the device through which a tympanostomy tube is placed across the tympanic membrane	Same	Same	No difference
Operation Mechanism	Automated	Manual	Automated	The subject device utilizes an automated mechanism that is the same as the reference device.
Distal Tip Configuration	Stainless steel shaft with a transparent polycarbonate tip	Stainless steel shaft	Stainless steel shaft with a transparent polycarbonate tip	The subject device has the same distal tip configuration as the reference device
Tympanostomy Tube (TT) Material	Medical grade silicone and colorant	Medical grade silicone and colorant	Medical grade silicone and colorant	The TT materials are similar to the predicate device.
Use	Single Use, disposable	Same	Same	No difference
Sterilization	ETO	Same	Same	No difference
Biocompatibility (ISO 10993-1)	Biocompatible	Same	Same	No difference

The subject device TDD and the predicate device HTTS have the same intended use and principle of operation, similar material composition, biocompatibility, clinical performance and some aspects of technological characteristics.

The Tula TDS (K171239) device is selected as the reference device to address the safety and effectiveness of differences in technological characteristics and patient population between subject and predicate devices. The Tula TDS (K171239) device is an earlier version of TDD (subject device), supports the safety and effectiveness of tube design (lateral and medial retention), distal tip configuration, and operation mechanism of the TDD.

Biocompatibility:

The TDD is comprised of materials that are commonly used in medical device applications. Biocompatibility evaluations have been conducted in accordance with ISO 10993-1 and FDA Guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process”. The TDD was categorized separately due to differences in patient contact duration; the Tula tympanostomy tube is classified as an implant with permanent (>30 days) contact with tissue and the delivery device as an external communicating device, contacting tissue for a limited contact duration.

Sterility:

The TDD is provided sterile and is intended for single use only. Sterility will be achieved via Ethylene Oxide (EO) to provide a minimum sterility assurance level (SAL) of 10^{-6} . The sterilization method was previously approved for a PMA device.

Performance Data (Bench Testing):

Bench verification testing is provided which verifies that the subject device meets the design user requirement and intended use. The tube deployment test, tube deployment time upon actuation, sound level test, button force test, the ability for the packaging to maintain product integrity and system level functionality without compromising the sterile barrier system were performed to support substantial equivalence.

Performance Data (Clinical Testing):

The following clinical study data was provided to support substantial equivalence.

Study 1: Tula TDD Retrospective Data Collection (With Topical Local Anesthesia)

Study 1 was a retrospective, observational review of real-world data (RWD) evaluating the safety and performance of tympanostomy tube placement using the Tula TDS with phenol as local anesthesia in a physician's office setting. Sixty children, ages 6 months to 16 years (mean age 2.80 years), were included. The cohort consisted of 26 children aged 6 months—<2 years (mean age 1.20 years) and 34 children aged 2–16 years (mean age 4.03 years). Overall, 96.7% were bilaterally indicated for tube placement. Immobilization was used for children under 10 years, and phenol was applied for topical anesthesia prior to tube placement with the TDS.

Results:

- **Procedural success:** 100% (60/60) of children received tubes in all indicated ears in the office as planned.
- **Usability:** 100% (118/118) tube placements were completed using the TDS without additional instruments.
- **Procedure tolerability:** 100% of children were documented to have tolerated the procedure well based on physician assessment of patient disposition.
- **Tube retention and patency (by ear) at first follow-up, approximately 1 month post-procedure:**
 - **Tube retention:** 95.5% (105/110)
 - **Tube patency:** 94.5% (104/110)
- **Adverse events:** No procedural adverse events occurred.
 - Additional adverse events were recorded at the first follow-up, approximately 1 month post-procedure that occurred at a low rate and were consistent with known risks of tympanostomy tube placement.

Study 2: TDS With the Tula Iontophoresis System and TYMBION[®]

Study 2 was a non-randomized, multicenter study evaluating both iontophoretic anesthesia with TYMBION[®] via the Tula Iontophoresis System (IPS) and subsequent tympanostomy tube delivery using the Tula TDS. All children were treated in a physician's office without sedation, anxiolytics, or papoose restraints. The pivotal cohort included 222 pediatric patients, and an additional 47 lead-in cases contributed to the safety analysis.

Results (pivotal cohort):

- **Procedural success:** 87.4% (194/222) of children received tubes in all indicated ears.
- **Usability:** 98.7% (379/384) tube placements were completed using the TDS without additional instruments.
- **Procedure tolerability:** Tube placement tolerability met predefined performance criteria, with mild, transient pain reported.
- **Pediatric distress:** Pediatric distress scores were low during tube placement and decreased following tube placement.
- **Tube retention and patency at 3 weeks post-procedure:**
 - **Tube retention:** 99.5%
 - **Tube patency:** 95%
- **Time to tube extrusion or removal:** Mean 16.72 months (median 15.77 months).
- **Adverse events:** There were no device, drug, or procedure-related serious adverse events in any Pivotal Study subjects.
 - Additional adverse events were recorded within the first month post-procedure that occurred at a low rate and were consistent with known risks of tympanostomy tube placement.

Substantial Equivalence and Conclusion:

When considering the totality of clinical data, including retrospective real-world data and prospective pivotal clinical data, in-office tympanostomy tube placement using the Tula TDD demonstrated high procedural success and tube delivery, and a favorable safety profile. Procedural success and tube delivery rates were high across pediatric age groups, with no device-related serious adverse events reported and low rates of non-serious, procedure-related adverse events consistent with known tympanostomy tube sequelae.

The legally marketed predicate device demonstrated successful in-office procedure completion rates of 98.9% in children aged 6–24 months and 95.8% in children aged 2–17 years. Successful tube delivery was achieved using the device without additional instruments to manipulate the tube into place in 96.9% and 90.3% of ears in these respective age groups. There were no reported procedure-related adverse events. The clinical performance of the Tula TDD when compared to the legally marketed predicate device with respect to procedural success, tube delivery effectiveness, and safety is comparable.

The predicate and subject devices have the same intended use and principle of operation and utilize similar materials with established biocompatibility. Although certain technological differences exist between the subject and predicate devices, these differences were evaluated through a comparison of technological and performance characteristics and a review of clinical performance data. The clinical performance results demonstrate that the subject device performs as intended without introducing additional safety risks. Furthermore, the technological characteristics of the subject device are consistent with those previously cleared under K171239. Based on this evaluation, the identified differences do not raise new or different questions of safety and effectiveness. Therefore, the subject device is substantially equivalent to the predicate device.