DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993 - 0002

June 28, 2017

Tusker Medical
Pavan Sethi
Director, Regulatory Affairs
155 Jefferson Drive Suite 200
Menlo Park, California 94025

Re: K171239
Trade/Device Name: TULA Tube Delivery System
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy Tube
Regulatory Class: Class II
Product Code: ETD
Dated: June 1, 2017
Received: June 2, 2017

Dear Pavan Sethi:

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. 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.

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 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Eric A. Mann -S

for Malvina Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K171239

Trade Name: TULA® Tube Delivery System

Common Name: Tympanostomy Tube and Tympanostomy Tube Delivery System

Indications For Use: The Tula Tube Delivery System is intended to provide a means to create a myringotomy with insertion of a preloaded Grommet type tympanostomy tube.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

Sponsor/Submitter:	Tusker Medical 155 Jefferson Drive, Suite 200 Menlo Park, California 94025
Contact Person:	Pavan Sethi, Ph.D. Director, Regulatory Affairs Phone: (408) 513-7529 Fax: (650) 223-6769
Date of Submission:	April 26, 2017
Device Trade Name:	TULA® Tube Delivery System
Common Name:	Tympanostomy Tube and Tympanostomy Tube Delivery System
Device Classification:	Class II
Regulation Number:	21 CFR 874.3880
Classification Name:	Tube, Tympanostomy
Product Code:	ETD
Predicate Device:	Tympanostomy Tube Delivery System (K103595)
Device Description:	The Tula Tube Delivery System (TDS) is a device that penetrates the tympanic membrane and inserts the Grommet type tympanostomy tube with a button controlled activation. It is intended to provide a means to create a myringotomy with insertion of a preloaded grommet type tympanostomy tube.
Indications for Use:	The Tula Tube Delivery System is intended to provide a means to create a myringotomy with insertion of a preloaded Grommet type tympanostomy tube.
Technological Characteristics:	Tula Tube Delivery System is composed of four concentric components that cut, dilate, shield and stabilize. The cutter creates the myringotomy. The dilator opens the incision while the shield introduces the tympanostomy tube through the myringotomy. The subject device is identical to the predicate device in method of operation, materials and intended use. The aspects of the device that control the tympanostomy tube delivery (Cutter, Dilator, Shield, Plunger, Clear Tip, Outer Tube) are unchanged between the subject and predicate device.

	The main differences in technological characteristics are: the modified device will be pre-loaded with a Grommet style tympanostomy tube instead of a Paparella style tympanostomy tube, and the Tube Delivery System is slightly modified to accommodate and implant a Grommet type tympanostomy tube. These differences in technological characteristics do not raise different questions of safety and effectiveness than the predicate and do not render this device Not Substantially Equivalent (NSE).
Performance Data:	Bench verification testing was conducted to verify that the modified device meets the design inputs and intended performance characteristics. The testing included tube deployment test, tube deployment time upon actuation, hearing safety test, loudness discomfort level and diameteral interference. Sterilization of the modified TULA Tube Delivery System is validated per ISO 11135:2014 —"Sterilization of Health Care Products—Ethylene Oxide: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices". The method used for sterilization validation is the overkill (half-cycle approach) in a fixed chamber method per Annex B of ISO 11135:2014. Biocompatibility evaluation and testing conducted gave acceptable results per ISO 10993-1 and FDA Bluebook Memorandum G95-1.
Summary of Substantial Equivalence:	The subject device TULA Tube Delivery System is substantially equivalent to the predicate device in indication for use, performance, fundamental scientific technology, safety and effectiveness.