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

August 22, 2014

Preceptis Medical
% Mr. Keith Leland
VP of Research and Development
505 Highway 169 North, #365
Plymouth, MN 55441

Re: K133921
Trade/Device Name: Preceptis Tympanostomy Tube System
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy Tube
Regulatory Class: II
Product Code: ETD
Dated: July 21, 2014
Received: July 22, 2014

Dear Mr. Leland,

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 yours,

Tina Kiang -S

for Malvina B. 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): K133921

Device Name: Preceptis Tympanostomy Tube System

Indications For Use:

The Tympanostomy Tube System is intended to deliver a tympanostomy tube in tympanostomy procedures in which the patient is receiving a tympanostomy tube.

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Table 1. Updated 510(k) Summary

Submitter Information:	Preceptis Medical, Inc. 505 Highway 169 North, #365 Plymouth, MN 55441 763.568.7819
Contact:	Keith Leland, VP of R&D
Date Prepared:	21 July 2014
Trade Name	Hummingbird TTS
Product Code	ETD (21 CFR Part 874.3880)
Common Name	Preceptis Tympanostomy Tube System
Predicate Device	Heinz Kurz Trocar Ventilation Tube, 510(k) K071150
Device Description	The Preceptis Tympanostomy Tube System (TTS) which includes a tympanostomy tube inserter (TTI) with a preloaded ventilation tube, is a single-use, sterile manual surgical instrument which is used to create a myringotomy in the tympanic membrane and place a ventilation tube. The TTI comprises a handle with one or more tip assemblies which contain a sterile tympanostomy tube. Each tip assembly can be removably attached to the handle and includes a positioning rod and a ventilation tube pre-loaded inside the distal end of a sharpened sheath. Attaching the tip assembly to the handle also connects the sheath and actuator, allowing the user to retract the sheath by manually scrolling an actuator located on the handle. The user manually advances the sharpened sheath to create a myringotomy and simultaneously positions the ventilation tube within the myringotomy, always under direct visualization. The user then manually retracts the sharpened sheath away from the myringotomy using the manual actuator located on the handle. The retraction of the sheath releases the tube within the myringotomy. A first tip assembly can then be removed from the handle and replaced with a second preloaded tip assembly for bilateral procedures.
Indications For Use	The Tympanostomy Tube System is intended to deliver a tympanostomy tube in tympanostomy procedures in which the patient is receiving a tympanostomy tube.

Technological Characteristics	The TTS is intended to deliver a tympanostomy tube (also referred to as a ventilation 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, and suctioning. The TTI is a manual surgical instrument. The actions of creating the myringotomy, positioning the ventilation tube, and retracting the sheath surrounding the ventilation tube are all performed manually by the user. A comparison between the TTS and the predicate device shows that the technological characteristics as confirmed through dimensional attributes and the indications for use are substantially equivalent
Performance Data	The Preceptis Tympanostomy Tube System (TTS) includes a disposable tool designed to create a myringotomy incision and place a tympanostomy tube across the tympanic membrane in one surgical pass, thereby reducing surgical trauma for the patient. Preceptis Medical, Inc. conducted a prospective, treatment-only multicenter clinical study to evaluate the performance and the safety of the TTS. A total of 50 ears indicated for tympanostomy tube insertion were treated in 25 pediatric patients (mean age of 2.6 years, ranging from 6 months to 7.8 years) by 6 investigators at 3 study sites. All procedures were performed under general anesthesia. The success rate in performing the tympanostomy procedures was 100%. Tympanostomy tubes were successfully delivered in all 25 patients (50 ears). In 40/50 ears (80%), only the TTI was used for the tympanostomy procedure. In 10/50 ears (20%), either a pick or alligator clip was used for additional adjustment of the tympanostomy tube. In all cases, only a single TTI was used for each ear. At follow-up, between 15 and 60 days post-surgery, tube retention was 100%. There was one case of recurrent infection not associated with the TTS and three occluded tubes. An independent otolaryngologist reviewed the results of the trial and determined that there were no safety issues associated with the TTS. The Preceptis TTS met the study safety and performance criteria.