DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 23, 2015

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

Re: K142282
Trade/Device Name: Hummingbird™ Tympanostomy Tube System (TTS)
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy Tube
Regulatory Class: Class II
Product Code: ETD
Dated: November 13, 2014
Received: November 14, 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" (21CFR 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,

William H. Maisel -S

William H. Maisel, MD, MPH
Director, Office of Device Evaluation (Acting)
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142282

Device Name
Hummingbird™ Tympanostomy Tube System

Indications for Use *(Describe)*
The Hummingbird™ Tympanostomy Tube System is intended to deliver a tympanostomy tube in tympanostomy procedures in which the patient is receiving a tympanostomy tube.

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 – K142282

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:	23 April 2015
Trade Name	Hummingbird™ Tympanostomy Tube System (TTS)
Product Code	ETD (21 CFR Part 874.3880)
Common Name	Tympanostomy Tube Inserter with pre-loaded ventilation tube
Predicate Devices	Preceptis Tympanostomy Tube System, 510(k) K133921

510(k) Summary – K142282

Device Description	The Hummingbird™ 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 TTS includes 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 Hummingbird™ Tympanostomy Tube System is intended to deliver a tympanostomy tube in tympanostomy procedures in which the patient is receiving a tympanostomy tube.
Technical 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. A comparison between the TTS and predicate device shows that the devices are identical.

Performance Data	Clinical performance data was submitted to assess the performance of the device when placed under moderate sedation with local anesthetic. In two studies (an initial feasibility study followed by a multi-site study), a total of 69 children (136 ears) underwent tympanostomy procedures under moderate sedation using the Preceptis TTS. The mean age of the patients was 2.4 years (range of 8 months to 8.9 years). Results: • 100% of the children received ventilation tubes as planned. • There were no intra-operative adverse events, no unanticipated adverse events, and adverse event rates were well within peer-reviewed literature reported rates. • Moderate sedation was per definition from the ASA guidelines, Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia. • The moderate sedation regimen was determined by the surgeon and anesthesiologist. In these two studies, the surgeon and anesthesiologist chose to use nitrous oxide (50-70%) in all cases. • In the 1st study, there were 12 conversions (30%) from moderate sedation to general anesthesia due to surgical challenges. In the 2nd study, 2 cases (7%) were converted. The reduction in the conversion rate was likely due to increased surgical experience and design improvements to the TTS to improve visibility and repeatability. • In most cases during the study, the surgeon chose to use a local anesthetic on the tympanic membrane to reduce discomfort for the patient. Under moderate sedation, local anesthesia of the tympanic membrane should be used to reduce the risk of head movement and increase patient comfort.