June 5, 2020

Preceptis Medical, Inc
Steve Anderson
Chief Executive Officer
10900 89th Ave N
Suite 4
Maple Grove, Minnesota 55369

Re: K200952
Trade/Device Name: Hummingbird Tympanostomy Tube System
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy Tube
Regulatory Class: Class II
Product Code: ETD
Dated: April 4, 2020
Received: April 9, 2020

Dear Steve Anderson:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Shu-Chen Peng

for Michael J. Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200952

Device Name
Hummingbird® Tympanostomy Tube System

Indications for Use *(Describe)*
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 children 6-24 months old.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510k Summary

Submitter Information:	Preceptis Medical, Inc. 10900 89th Avenue North, Suite 4 Maple Grove, MN 55369 763.568.7819
Contact:	Steve Anderson, CEO
Date Prepared:	5 June 2020
Trade Name	Hummingbird® Tympanostomy Tube System (TTS)
Product Code	Ear, Nose and Throat Devices: ETD (21 CFR Part 874.3880)
Classification	Class II
Common Name	Tympanostomy Tube Inserter with pre-loaded ventilation tube
Predicate Devices	Preceptis Tympanostomy Tube System, K142282
Device Description	The Hummingbird® Tympanostomy Tube System (HTTS), which includes a preloaded ventilation tube, is a single-use, sterile manual surgical instrument. The HTTS is used to create a myringotomy in the tympanic membrane and place a ventilation tube. The surgeon manually advances the sharpened sheath to create a myringotomy and simultaneously positions the ventilation tube within the myringotomy, always under direct visualization. The surgeon 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.
Indications For Use	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 children 6-24 months old.

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Technical Characteristics	The HTTS is intended to deliver a tympanostomy tube (also referred to as a ventilation tube) through the tympanic membrane of the patient. It combines the separate functions of creating a myringotomy, positioning and placing a ventilation tube across the tympanic membrane.
Comparison to the predicate	The HTTS is identical to the predicate (except the removal of the suction feature), including the Intended Use. All other technological characteristics (e.g., design, material, chemical composition, functionality) are identical and non-clinical performance data tests (except shelf life testing) were not repeated from K142282. Shelf life of the device is increased to 27 months (supported by non-clinical testing). Indications for use are different from the predicate device as the subject device indications are expanded to include in-office use in children 6-24 months old.
Performance Data	In order to evaluate the pediatric-specific performance of the HTTS in an office setting, a multi-site clinical study in children 6-24 months old was performed. A total of 180 children (360 ears) underwent tympanostomy procedures in an ENT office using the HTTS. The mean age of the patients was 13 months (range of 6-24 months). Immobilization (papoose and/or swaddling with a nurse or MA holding the child's head) was used on all patients, and Phenol was used on 173 out 180 patients. Results: • 178/180 (98.9%) children received ventilation tubes in the office as planned. • The rate of procedural adverse events was 2/360 ears (0.56%), and there were no serious or unanticipated adverse events reported. • The median bi-lateral procedure time was 5:00 (range of 2:00–15:32). • The recovery of the child was evaluated by the ENT and staff, and 177/180 (98.3%) children were judged as calm and/or no inappropriate crying before leaving the clinic. • In 7 ears, tube delivery was completed using additional instruments to the HTTS. • 84.5% of ears were completed in one surgical pass; 97.7% were completed in two passes or less; and 2.3% required more than 2 passes.

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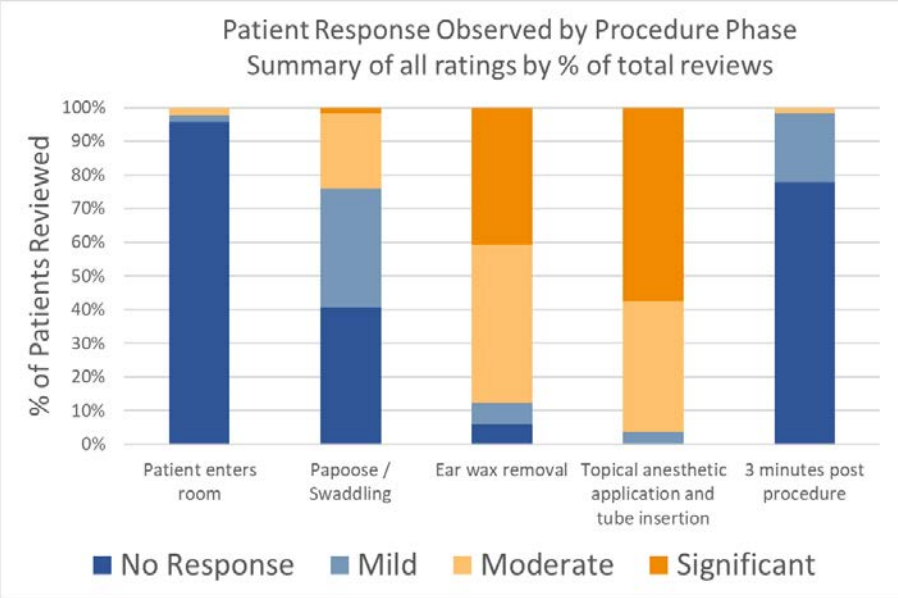
- In 130 parent surveys collected at follow-up, 93.1% of parents strongly agree or agree that it was important to have an alternative to general anesthesia and that they would recommend the HTTS office procedure to other parents.
- A committee of clinicians with ENT and/or pediatric specialty independently reviewed 18 procedure videos to evaluate how the child tolerated the procedure. At each stage of the procedure, the clinician reviewers rated the response of the child in the following categories: no response, mild, moderate or significant. In all 18 cases, each of the reviewers deemed that the child tolerated the procedure acceptably. A bar graph tabulation of the committee video review is as follows:



<u>Precautions for office use</u>

When using the HTTS for tympanostomy tube placement in children in an otolaryngology office setting:

- Assess suitability of the HTTS procedure using shared decision making between the parents and the physician.
- Local anesthesia should be used on the tympanic membrane to increase the child's comfort.
- Immobilization with a papoose and/or swaddling should be used to mitigate the child's body movement, and the head should be gently restrained by a nurse or medical assistant.

510k Summary

<table>
<tr>
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<td>A table comparing key clinical metrics between subject device and the predicate device (K142282) is shown below. These clinical results demonstrate substantial equivalence to the predicate device.
<table>
<tr><th>Clinical Metric</th><th>Pediatric Office Study</th><th>Predicate Conscious Sedation Study (K142282)</th></tr>
<tr><td>Median age of child</td><td>12 months</td><td>21 months</td></tr>
<tr><td>Successful rate in office or under sedation</td><td>98.9%</td><td>88.3%</td></tr>
<tr><td>Efficacy endpoint (HTTS delivery of tube)</td><td>96.9%</td><td>92%</td></tr>
<tr><td>Safety endpoint (procedural AE rate)</td><td>0.56%</td><td>0.0%</td></tr>
<tr><td>% ears completed in one surgical pass</td><td>84.5%</td><td>82%</td></tr>
<tr><td>Early extrusion rate</td><td>3.0%</td><td>3.2%</td></tr>
<tr><td>Plugging rate</td><td>11.3%</td><td>12.3%</td></tr>
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<td>Conclusion</td>
<td>The clinical performance data described above demonstrates that pediatric use in the office setting is as safe and as effective when compared to the predicate device (K142282).</td>
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