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

September 21, 2015

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

Re: K151830
Trade/Device Name: Hummingbird Tympanostomy Tube
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy Tube
Regulatory Class: Class II
Product Code: ETD
Dated: July 22, 2015
Received: July 23, 2015

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,

Eric A. Mann -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

Section 4
Indications For Use Statement

Indications for Use

510(k) Number (if known):

Device Name: Hummingbird™ Tympanostomy Tube

Indications For Use: Indicated where chronic Eustachian tube dysfunction does not respond to conventional therapy.

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)

_____
Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5
510k Summary

K151830

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:	1 July 2015
Trade Name	Hummingbird™ Tympanostomy Tube
Product Code	ETD (21 CFR Part 874.3880)
Common Name	Tympanostomy Tube
Predicate Device	Summit Medical Ventilation Tubes, 510(k) #K830228
Device Description	The tympanostomy tube is a silicone tube that is intended to provide ventilation and drainage to the middle ear.
Indications For Use	Indicated where chronic Eustachian tube dysfunction does not respond to conventional therapy.
Technological Characteristics	The tympanostomy tube is inserted through the tympanic membrane to allow for ventilation of the middle ear and the drainage of fluid.
Performance Data	The tympanostomy tube met all performance acceptance criteria.

Section 5
510k Summary

Overview of Device

The Hummingbird™ Tympanostomy Tube is a silicone tympanostomy tube.

It is intended to provide ventilation of the middle ear and drainage of fluids in instances where chronic Eustachian tube dysfunction does not respond to conventional therapy

The Hummingbird Tympanostomy Tube is preceded by the predicate: Summit Medical ventilation tubes (cleared under K830228). Similar to the predicate device, the Hummingbird Tympanostomy Tube is designed to be inserted using the Hummingbird Tympanostomy Tube System.

Substantial Equivalence Analysis

The key performance, safety and design characteristics of the devices that are used to establish equivalence are identified and are listed in the substantial equivalence table.

The device comparison table shows the similarities and differences between the Hummingbird™ Tympanostomy Tube and the predicate device. The indications for use for the devices are the same. The Hummingbird Tympanostomy tube is identical with respect to function and materials as the Summit Medical ventilation tubes. The Hummingbird Tympanostomy Tube is comparable dimensionally to Summit Medical ventilation tubes.

An analysis of the differences between the devices showed minor dimensional differences between the Hummingbird Tympanostomy Tube and the Summit Medical ventilation tubes. The devices are substantially equivalent.

Device Description

The Hummingbird™ Tympanostomy Tube consists of the following model:

Component/ Model	Description
Ventilation Tube/05-1026-009	Silicone Ventilation Tube

The ventilation tube is a standard, medical grade silicone otologic ventilation tube with a 1 mm inside lumen diameter as illustrated in diagram 1 (all dimensions are in millimeters.)

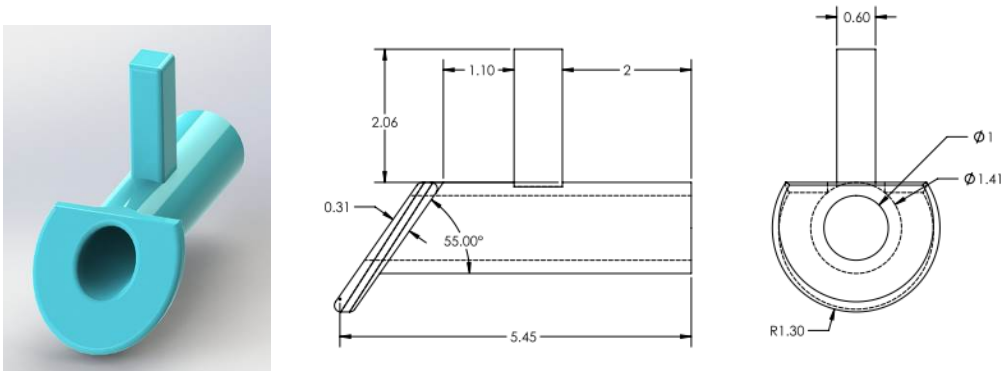

Diagram 1 – 05-1026-009

Section 5
510k Summary

Substantial Equivalence

The Hummingbird™ Tympanostomy Tube is substantially equivalent with respect to the Summit Medical predicate as confirmed through dimensional attributes and material equivalence.

The device comparison table shows the similarities and differences between the Hummingbird™ Tympanostomy Tube and the predicate. The indications for use, materials, and method of sterilization are all the same.

Device Comparison Table

Parameter	Hummingbird™ Tympanostomy Tube (PN 05-1026-009)	Summit Medical Otologic Ventilation Tubes - Predicate	Comparison
General Description	Ventilation Tube	Ventilation Tube	
Indications for Use	Indicated where chronic Eustachian tube dysfunction does not respond to conventional therapy.	Indicated where chronic Eustachian tube dysfunction does not respond to conventional therapy.	Same
Intended use	Indicated where chronic Eustachian tube dysfunction does not respond to conventional therapy.	Indicated where chronic Eustachian tube dysfunction does not respond to conventional therapy.	Same
Design	Silicone ventilation tube	Silicone ventilation tube	Same
Technological Characteristics	Silicone vent tube to be placed across the tympanic membrane to allow for middle ear ventilation and fluid drainage.	Vent tube to be placed across the tympanic membrane to allow for middle ear ventilation and fluid drainage.	Same
Dimensions (vent tube)	1 mm lumen diameter	0.89-1.14 mm lumen diameter	Similar
Materials	Medical Grade Silicone	Medical Grade Silicone	Same
Sterile	Sterile (EO)	Sterile (EO)	Same

Summary of Similarities

- Indications for use are the same.
- Design and Technological Characteristics are the same.
- Materials are the same.
- Method of sterilization is the same.

Summary of Differences

- There are minor dimensional differences between the Hummingbird Tympanostomy Tube and the Summit Medical predicate tubes, but the dimensions of the Hummingbird tube fall within the range covered by the predicates.

An analysis of the differences between the devices does not raise a question of safety or efficacy. The devices are substantially equivalent.