May 20, 2024

AventaMed DAC
Keith Jansen
President and CEO
Rubicon Centre, Rossa Avenue,
Bishopstown, Cork T12 Y275
Ireland

Re: K232702
Trade/Device Name: Solo+ Tympanostomy Tube Device (TTD)
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy Tube
Regulatory Class: Class II
Product Code: ETD
Dated: April 19, 2024
Received: April 19, 2024

Dear Keith Jansen:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232702

Device Name
Solo+ Tympanostomy Tube Device (TTD)

Indications for Use *(Describe)*
The Solo+ Tympanostomy Tube Device 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 pediatric patients 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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510(k) Summary

General Information

Date Prepared:	20th May 2024
Classification:	Class II, 21 CFR 874.3880 Tympanostomy Tube
Product Code:	ETD
Trade Name:	Solo+ Tympanostomy Tube Device (TTD)
Common Name:	Tympanostomy Tube
Model Numbers:	Solo+ Tympanostomy Tube Handpiece (Catalogue#: 12115-100-000) Solo+ Tympanostomy Tube Cartridge (Catalogue#: 12115-200-000)
Owners Name	AventaMed DAC Rubicon Centre Rossa Avenue Bishopstown Cork T12 Y275 Ireland
Contact Person:	Keith Jansen, President and CEO
AventaMed DAC:	Rubicon Centre Rossa Avenue Bishopstown Cork T12 Y275 Ireland Tel: +353 21 492 8980 Email: keith.jansen@aventamed.com

Intended Use

The Solo+ Tympanostomy Tube Device is intended to deliver a tympanostomy tube through the tympanic membrane (TM) of the patient. It combines the separate functions of creating a myringotomy, and positioning and placing a ventilation tube across the TM.

Indications for Use

The Solo+ Tympanostomy Tube Device 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 pediatric patients 6-24 months old.

Predicate Device

- Hummingbird Tympanostomy Tube System (HTTS), Preceptis Medical Inc. (K200952)

Reference Device

- Otological Ventilation Tube - Sheehy Design, Micromedics, Inc. (K830228)

Device Description

The Solo+ Tympanostomy Tube Device TTD (Solo+ TTD) is a single use, sterile, “all-in-one” surgical instrument that rapidly places a tympanostomy tube across the tympanic membrane of a patient. It combines the traditionally separate functions of creating a myringotomy, and positioning and placing a tympanostomy tube across the tympanic membrane. Placement of the tube provides ventilation to the middle ear space through the tympanic membrane.

To use the device, the user creates a myringotomy with the device’s myringotomy knife, which is located at its distal tip of the Cartridge. The user advances the device until the tympanostomy tube outer flange reaches the tympanic membrane. The user then actuates the device by pressing the activation button on the Handpiece. This retracts the myringotomy knife construct and deploys the tube across the tympanic membrane.

Materials

The Solo+ TTD is comprised of materials that are commonly used in medical device applications. The biological safety tests were performed in accordance with ISO 10993-1 (Biological evaluation of medical devices -- Part 1: Evaluation and testing). For testing the device has been categorized in two parts, the Solo+ Delivery System which has a category of a surface device contacting breached or compromised surfaces and the Solo+ Tympanostomy Tube which has a category of Implant Device contacting tissue/bone.

The tests performed to demonstrate the biocompatibility of the device were:

- Physical and Chemical Characterization
- Cytotoxicity
- Sensitization
- Irritation / Intracutaneous Reactivity
- Acute Systemic Toxicity
- Subchronic Toxicity
- Subacute Toxicity
- Implantation Short-Term and Long Term
- Material- Mediated Pyrogenicity

Comparison of Technological Characteristics of Solo+ TTD compared to the Predicate Device (Preceptis, Hummingbird TTS) and Reference Device (Micromedics, Otological Ventilation Tube - Sheehy Design)

The Solo+ TTD and the equivalent commercialized predicate device Preceptis Hummingbird TTS were evaluated for substantial equivalence. No significant difference in clinical, technical, and biological parameters was identified between the devices. Both devices have the same intended patient and user populations and intended use; to deliver a tympanostomy tube through the tympanic membrane of the patient. Both devices combine the separate functions of creating a myringotomy, and positioning and placing a ventilation tube across the tympanic membrane. Technological equivalence is demonstrated via comparative test data and assessment of the

primary technological characteristics. Biological equivalence is demonstrated via reference to the material used in each device and the biocompatibility testing which demonstrates that the devices are biologically safe for their intended use.

Where there is a difference in geometry of the tympanostomy tube to the Preceptis Hummingbird TTS tympanostomy tube, equivalence is demonstrated to the reference device; the Micromedics Otological Ventilation Tube - Sheehy Design via review of the appropriate technological characteristics.

Via the comparative analysis and the test data generated and reviewed, the Solo+ TTD Device has been shown to be substantially equivalent to the commercialized Hummingbird TTS.

Non-Clinical Information

The determination of substantial equivalence is also based on an assessment of non-clinical engineering tests, as listed in **Table 1** and **Table 2.**

Table 1: List of Design Verification Tests

Design Verification Tests	
Device Visual and Dimensional Checks	Packaging testing
Device Puncture Measurement	Biocompatibility Testing
Simulated Use Testing	MRI safety testing
Cartridge Functional Tests	Sterilization Validation
Handpiece Functional Tests	Residuals testing
Aging Testing	Bioburden & Endotoxin Validation
Transportation Testing	

Table 2: List of Design Validation Tests

Design Validation Tests	
IFU/Label comprehension	Device placement
Package suitability	Device ease of use
Device functionality testing	Device Disposal
Visualization assessment	

The test results demonstrate that the Solo+ TTD Device meets the requirements in the applicable standards and specifications and is substantially equivalent to a legally marketed predicate device.

Clinical Information

A clinical study using the Solo+ TTD has demonstrated substantial equivalence to the predicate device, Preceptis Hummingbird TTS intra-operatively and through 1st post-operative follow-up in an in-office setting.

In-office setting: 6-24 months old.

In a multi-site study, a total of 20 patients (40 ears), underwent tympanostomy procedures using the Solo+ TTD across 2 sites in an in-office setting with topical anesthesia and protective stabilization. The mean age of the patients is 12.5 months (range 6 to 19 months) and a median age of 12.5 months.

Results:

- 20/20 (100%) children received tympanostomy tubes as planned (success)
- There were no device or procedure related serious adverse events.
- 87.5% (35/40) of ears were completed using only the Solo+ TTD without the need for additional instruments to aid in the placement.

The clinical data described above demonstrates that in an in-office setting, the Solo+ TTD is as safe and as effective as the Hummingbird TTS in pediatric patients 6-24 months old. A table comparing study endpoint results with the comparative study for the Hummingbird TTS (K200952) is shown in **Table 3**.

Table 3: Study endpoints compared between Solo+ TTD and Hummingbird TTS

Clinical Outcome	AventaMed DAC Solo+ TTD	Preceptis Hummingbird TTS (K200952)
Successful Placement of the Device without need for an operating room procedure	100 % (20/20 patients)	98.9%
Delivery Success (placed without the need for additional instruments to aid in placement of the device)	87.5% (35/40 ears)	96.9%

Conclusion

These clinical results, together with the comparison of technological and performance characteristics, demonstrate that there are no differences between the two devices that raise different questions of safety and effectiveness relevant to use of the Solo+ TTD in an office setting. The Solo+ TTD has been demonstrated to be substantially equivalent to the Hummingbird TTS.