April 30, 2025

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

Re: K250256
Trade/Device Name: Solo+ Tympanostomy Tube Device (TTD), Solo+ TTD, Solo+ (Solo+ Tympanostomy Tube Handpiece (Catalogue #: 12115-100-000) and Solo+ Tympanostomy Tube Cartridge (Catalogue #: 12115-200-000))
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy tube
Regulatory Class: Class II
Product Code: ETD

Dear Keith Jansen:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 28, 2025. Specifically, FDA is updating this SE Letter to correct the Indications for Use (IFU) form.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Shu-Chen Peng, Ph.D., OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, (301) 796-6481, shu-chen.peng@fda.hhs.gov.

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

April 28, 2025

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Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy Tube
Regulatory Class: Class II
Product Code: ETD
Dated: January 28, 2025
Received: January 28, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

Device Name

Solo+ Tympanostomy Tube Device (TTD), Solo+ TTD, Solo+ (Solo+ Tympanostomy Tube Handpiece (Catalogue #: 12115-100-000) and
Solo+ Tympanostomy Tube Cartridge (Catalogue #: 12115-200-000))

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 months and older.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

General Information

Date Prepared:	April 28, 2025
Classification:	Class II, 21 CFR 874.3880 Tympanostomy Tube
Product Code:	ETD
Trade Name:	Solo+ Tympanostomy Tube Device (TTD) Solo+ TTD Solo+
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

Traditional 510(k) Premarket Notification Submission:
Solo+™ Tympanostomy Tube Handpiece and Solo+™ Tympanostomy Tube Cartridge

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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 months and older.

Predicate Devices

- Primary Predicate: Solo+ Tympanostomy Tube Device (TTD), AventaMed DAC (K232702)
- Secondary Predicate: Hummingbird Tympanostomy Tube System (HTTS), Preceptis Medical Inc. (K221254)

Device Description

The Solo+ Tympanostomy Tube Device (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 (blue) 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 (Proposed Device) compared to the Primary Predicate Device (K232702) and Secondary Predicate Device (Preceptis, Hummingbird TTS - Tympanostomy Tube)

No significant difference in intended use, indications for use, and technological characteristics were identified between the Solo+ TTD (proposed device) and the commercialized primary predicate device (K232702) and the secondary predicate device (K221224).

Solo+ TTD (proposed device) has the same intended use as both the primary predicate device (K232702), and the Hummingbird® Tympanostomy Tube System (secondary predicate device) of 'intended to deliver a tympanostomy tube through the tympanic membrane (TM) of the patient' and can be considered equivalent. The Solo+ TTD (proposed device) and predicate devices (K232702 and K221224) combine the separate functions of creating a myringotomy, and positioning and placing a ventilation tube across the TM.

The intended patient population for the new Solo+ TTD has been expanded to include pediatric patients 6 months and older. The primary predicate device is indicated for pediatric patients 6 months – 24 months of age (K232702), whereas the Hummingbird (K221224) has the same intended population as the subject device. The Solo+ TTD (proposed device) and predicate devices (K232702 and K221224) have the same intended use; to deliver a tympanostomy tube through the tympanic membrane of the patient. The Solo+ TTD (proposed device) and predicate devices (K232702 and K221224) combine the separate functions of creating a myringotomy, and positioning and placing a ventilation tube across the tympanic membrane.

Traditional 510(k) Premarket Notification Submission:
Solo+™ Tympanostomy Tube Handpiece and Solo+™ Tympanostomy Tube Cartridge

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Technological equivalence is demonstrated via comparative test data and assessment of the primary technological characteristics of the primary predicate device (K232702) and secondary predicate device (K221224). 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.

Table 1 Comparison of Solo+ TTD subject device, and predicate devices Solo+ TTD (K232702) and Hummingbird TTS (K221224)

	AventaMed DAC (Proposed Device)	**AventaMed DAC (Primary Predicate Device)**	**Preceptis Medical (Secondary Predicate Device)**
"All in one" Tympanostomy Tube System			
Trade Name	Solo+ Tympanostomy Tube Device (TTD) Solo+ TTD Solo+	Solo+ Tympanostomy Tube Device (TTD) Solo+ TTD Solo+	Hummingbird® Tympanostomy Tube System (HTTS)
510(k) Number	K250256	K232702	K221254
Classification	Class II	Class II	Class II
Product Code	ETD	ETD	ETD
Clinical Characteristics			
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 months and older.	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.	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 in pediatric patients 6 months and older.
Single-Patient Use	Yes	Yes	Yes
Technological Characteristics			
Sterile	Yes	Yes	Yes
Components	• Handpiece	• Handpiece	• Handle Tip assembly with retractable

	AventaMed DAC (Proposed Device)	AventaMed DAC (Primary Predicate Device)	Preceptis Medical (Secondary Predicate Device)
	• Cartridge assembly with retractable myringotomy knife and pre-loaded tympanostomy tube	• Cartridge assembly with retractable myringotomy knife and pre-loaded tympanostomy tube	cutting sheath and pre-loaded tympanostomy tube
Myringotomy Technique	Manual	Manual	Manual
Activation Method	Push button	Push button	Slider button
Biological Characteristics			
Tympanotomy Tube (Implant)	• Medical Grade silicone • Stainless Steel	• Medical Grade silicone • Stainless Steel	• Medical Grade silicone

Non-Clinical Information

The determination of substantial equivalence is also based on an assessment of non-clinical engineering tests completed on the Primary Predicate Device (K232702), as listed in **Table 2** and **Table 3.**

Table 2: 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 3: 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 (proposed device) meets the requirements in the applicable standards and specifications and performance was identical to the legally marketed predicate device (K232702).

Clinical Information

A clinical study using the Solo+ TTD (proposed device) supports substantial equivalence to the predicate devices (K232702 and K221224) through the first post-operative follow-up in an in-office setting.

In-office setting: ≥24 months old

In a multi-site study, a total of 20 pivotal cohort patients (36 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 was 4.5 years (range 2 to 9 years) and a median age of 4.0 years.

Results:

- 18/20 (90%) children received tympanostomy tubes as planned (success)
- There were no device or procedure related serious adverse events.
- 86.1% (31/36) of ears were completed using only the Solo+ TTD without the need for additional instruments to aid in the placement.
- Protective stabilization was used in 80% (16/20) of patients ≥24 months old (papoose, swaddle and/or holding of the head/body).

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 ≥24 months old. A table comparing study endpoint results for the Solo+ TTD in pediatric patients age >2 years with the study of Solo+ TTD in pediatric patients age ≥6 to <24 months (K232702) primary predicate device and to a comparative study for the Hummingbird TTS (K221254) secondary predicate device in patients 2 years and older is shown in **Table 4**.

Table 4: Study endpoints compared between Solo+ TTD subject device, and predicate devices Solo+ TTD (K232702) and Hummingbird TTS (K221224)

Clinical Outcome	**AventaMed DAC Solo+ TTD** ≥ 24 months	**AventaMed DAC Solo+ TTD** (K232702) ≥ 6 to < 24 months	**Preceptis Hummingbird TTS** (K221254) ≥ 2 years
Successful Placement of the Device without need for an operating room procedure	90 % (18/20 patients)	100 % (20/20 patients)	95.8% of patients
Delivery Success (placed without the need for additional instruments to aid in placement of the device)	86.1% (31/36 ears)	87.5% (35/40 ears)	90.3% of ears

Conclusion

These clinical results, together with the comparison of technological and performance characteristics, demonstrate that there are no differences that raise different questions of safety and effectiveness relevant to use of the Solo+ TTD in an office setting. The Solo+ TTD (proposed device) has been demonstrated to be substantially equivalent to the predicate devices (K232702 and K221254).