August 3, 2023

Spiggle & Theis Medizintechnik GmbH
Claudia Winterschladen
Head of Regulatory Affairs International
Burghof 4
Overath, North Rhime-Westphalia 51491
Germany

Re: K223542
Trade/Device Name: TubaVent Balloon Dilatation System
Regulation Number: 21 CFR 874.4180
Regulation Name: Eustachian Tube Balloon Dilation System
Regulatory Class: Class II
Product Code: PNZ
Dated: June 30, 2023
Received: July 3, 2023

Dear Claudia Winterschladen:

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,

Joyce C. Lin -S

for 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)*
K223542

Device Name
TubaVent Balloon Dilatation System

Indications for Use *(Describe)*
The TubaVent balloon dilatation system is intended to dilate the cartilaginous portion of the Eustachian tube for treatment of persistent obstructive Eustachian tube dysfunction in patients 18 years 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.

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Section 5 - 510(k) Summary

as required by 21 CFR 807.92(c)

1. Owner of the 510(k) [807.92(a)(1)]

Manufacturer / 510(k) Submitter	Spiggle & Theis Medizintechnik GmbH Burghof 4 51491 Overath / Germany
Establishment Registration Number	3002858762
Phone / Fax number	+49 2206 9081-65 / +49 2206 9081-13
Contact Person for 510(k)	Claudia Winterschladen Head of Regulatory Affairs International Email: c.winterschladen@spiggle-theis.com
Date, 510(k) summary was prepared	2022-11-10

2. Device Identification [807.92(a)(2)]

Device Trade Name	TubaVent Balloon Dilatation System
Device Common or Usual Name	N/A
Classification/Regulation Name	Eustachian Tube Balloon Dilation System
Device Regulation Number	21 CFR 874.4180
Device Classification Product Code	PNZ
Device Class	Class II
Regulation Medical Specialty / Review Panel	Ear, Nose & Throat

3. Predicate Device [807.92(a)(3)]

Manufacturer / 510(k) Submitter	Acclarent Inc.
510(k) No.	K171761
Device Trade Name	Acclarent Aera®
Device Common or Usual Name	N/A
Classification / Regulation Name	Eustachian Tube Balloon Dilation System
Device Regulation Number	21 CFR 874.4180
Device Classification Product Code	PNZ
Device Class	Class II
Regulation Medical Specialty / Review Panel	Ear, Nose & Throat

4. New Device Description [807.92(a)(4)]

Description	The TubaVent balloon dilatation system is an Eustachian Tube Balloon Dilation System consisting of the balloon catheter, the TubaInsert insertion device and the inflation device. It is used for dilation of the cartilaginous portion of the Eustachian tube in persistent obstructive Eustachian tube dysfunction. The balloon catheter TubaVent is available in two versions where the balloon diameter is different: 3 and 4.5 mm. The insertion device TubaInsert has an angle of 45° at the distal end.
How it functions	The balloon is located at the distal end of the TubaVent and is inflated using sterile isotonic saline solution NaCl 0.9 % to 10 bar. The inflation is controlled with help of the pressure gauge on the inflation device. The balloon pressure is then hold for 2 minutes. Insertion of the TubaVent into the Eustachian tube (ET) is done with the TubaInsert via a patient's nostril. The procedure is usually carried out under general anesthesia. Evidence is emerging in the scientific literature that the procedure can be done under local anesthesia, sedation, and analgesia. Real-world clinical data collected in a pilot feasibility study from 10 patients (5 received bilateral BET) supports the use of the TubaVent short device under local anesthesia. The use of local anesthesia for this procedure is evident with appropriate patient preparation, which may include supplemental medication for patient management.[1]
Scientific concept	Eustachian tube dysfunction (ETD) is a common condition resulting from inadequate opening of the Eustachian tube or the inability to appropriately equalize pressure between the middle ear and the environment, respectively. This may lead to hearing loss, chronic otitis media, tinnitus, and vertigo. The principle of dilatation to open an obstructed tube has been successfully applied for many years for example in blood vessels. The marketing of the first Eustachian balloon dilation catheter was permitted by the FDA in September 2016. The decision was based on a randomized clinical trial in which 52 % of treated patients had tympanogram results within a normal functioning range six weeks after the procedure compared to 14 % of the patients, who were treated with conventional medical management (nasal spray).
Significant physical and performance	The TubaVent balloon dilatation system is offered with two different balloon diameters, 3.0 and 4.5 mm. The balloons are both 20 mm long

[1] Luukkainen V, Jero J, Sinkkonen ST. Balloon Eustachian tuboplasty under monitored anaesthesia care with different balloon dilation devices: A pilot feasibility study with 18 patients. Clin Otolaryngol. 2019 Jan;44(1):87-90. doi: 10.1111/coa.13236. Epub 2018 Nov 4. PMID: 30281926.

characteristics (design, material etc.)	and are made of polyamide. The balloon is semi-compliant. The working length of the catheter is for both variants 236 mm.

5. Intended Use New Device [807.92(a)(5)]

Intended use and patient population	The TubaVent balloon dilatation system is intended to dilate the cartilaginous portion of the Eustachian tube for treatment of persistent obstructive Eustachian tube dysfunction in patients 18 years and older.

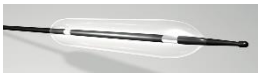
6. Summary technological characteristics compared to predicate [807.92(a)(6)]

Characteristics	New device	Predicate device	Correspondence
Catheter			
Catheter Total Length [mm]	270	327	Different: The TubaVent balloon dilatation system is shorter thus perfectly adapted to the insertion instrument TubaInsert, which prevents the catheter from being pushed too far into the Tuba Eustachii.
Catheter Working Length [mm]	236	Not known	See explanation in previous line.
Distal shaft end (balloon)	flexible	flexible	Identical
Proximal shaft end	Hypotube made of stainless steel	Hypotube, rigid	Identical: In both devices the proximal shaft is a rigid hypotube
Insertion / Shaft marker	No, because the protruding length of the TubaVent Balloon out of the TubaInsert is fixed by design features.	Yes	Different: The length of the TubaVent protruding from the TubaInsert is fixed. After the proximal end of the TubaVent has come into contact with the

Characteristics	New device	Predicate device	Correspondence
			proximal end of the TubaInsert, further advancement out of the TubaInsert is not possible and therefore no shaft marker is required. Therefore, this difference does not cause any new issue of safety or effectiveness of the new device.
Actuator	No	Yes	Different: The function of the actuator of the predicate device is to facilitate single-handed advancement and retraction of balloon catheter, if required. The balloon catheter of the predicate device can also be moved forward with two hands. Furthermore, the usability study confirmed that the two hand procedure of the new device does not cause new safety issues as the movement of the catheter is done under endoscopic control.
Balloon catheter design	Dual lumen tubing: outer lumen is used to expand the balloon	Dual lumen tubing	Identical
Inflation connection	Luer connector	Luer connector	Identical
Balloon			
Length x Diameter [mm] at working pressure	- Short: 3.28 x 20.0 - Short wide: 4.94 x 20.0	6.0 x 16.0	Similar: The TubaVent balloon has a smaller diameter and is 4 mm longer than the predicate. A smaller

Characteristics	New device	Predicate device	Correspondence
			diameter is less traumatic and a longer balloon ensures that a longer part of the cartilaginous part of the ET (approx. 24 mm long) is dilated.
Type	Semi-compliant	Non-compliant	Different: Semi-compliant balloons provide more compliance than a non-compliant balloon and more flexibility to ease delivery than a non-compliant balloon. Schubert et al. published a comparison of the balloons in 2018[2], which shows that the Acclarent Aera balloon also behaves like a semi-compliant balloon. Thus, both balloons are equivalent, although Acclarent describes its balloon as non-compliant.
Material	PA (Polylauryllactam; nylon)	PET (Polyethylene terephthalate; polyester)	Similar, as both materials are thermoplastic and chemically inert or chemically resistant, respectively.
Catheter tip			

[2] Schubert J, Wilfling T, Schümann K, Paasche G, Grabow N, Schmitz K-P, Lenarz T, Schmidt W. Investigation of balloon dilatation devices for treatment of Eustachian tube dysfunction. Current Directions in Biomedical Engineering 4(1): 529-533, 2018.

Characteristics	New device	Predicate device	Correspondence
Design	Olive-shaped; 1.2 mm in diameter; atraumatic 	Ball-shaped; 2.4 mm in diameter; atraumatic	Similar: Both designs prevent catheter travel into the isthmus
Material	Pebax	Nylon	Similar: Both materials are soft and therefore atraumatic.
Insertion Device			
Separate	Yes: TubaInsert	Yes	Identical
Rigid shaft	Yes, hypotube	Yes, hypotube	Identical
Angled tip	Yes	Yes	Identical
Atraumatic tip	Yes	Yes	Identical
Distal angled tip	Yes	Yes	Identical
Inflation device			
Name	Inflation device	Acclarent Balloon Inflation device	N/A
Photo			Similar in design and shape
Indications for use	The inflation device (…) is intended to inflate, deflate and monitor pressure in the TubaVent.	The ACCLARENT® Balloon Inflation Device is used to inflate the balloon.	Similar wording with identical meaning
Syringe volume	30 cc	20 cc	Different
Pressure gauge	Atm and PSI	Atm and PSI	Identical
Length (Plunger not extended)	23.9 cm	8.1” [≙ 20.575 cm]	Different due to the greater volume of the subject device.

Characteristics	New device	Predicate device	Correspondence
Length (Plunger extended)	34.9 cm	11.3" [≙ 28.702 cm]	Different due to the greater volume of the subject device.

7. Non-clinical Tests: Bench [807.92(b)(1)]

Biocompatibility	- ISO 10993-5:2009 (Cytotoxicity) - ISO 10993-10: 2010 (Sensitization & Irritation) - ISO 10993-11: 2017 (acute systemic toxicity) - ISO 10993-23: 2021 (sensitization) All tests were passed. The TubaVent balloon dilatation system fulfils all applicable biocompatibility requirements. The material used for this device is not cytotoxic. It does not cause sensitization, irritation or intracutaneous reactivity nor does it cause acute systemic toxicity.
Performance	All performance tests have demonstrated that the TubaVent balloon dilatation system performs as intended. Tests include dimensional verification, deflation time, balloon burst pressure, tensile strength, torque and fatigue tests. Simulation studies in a head model and in an animal cadaver model (sheep head) have ensured that the TubaVent balloon dilatation system functions in accordance with its design specifications and intended use. A human cadaver study was executed in order to fulfil the special control of 874.4180(b)(iv)(6). TubaVent balloon dilatation system. This human factors validation testing demonstrated that the device can be used by the intended users without serious use errors or problems, for the intended uses and under the expected use conditions. The results confirm that the TubaVent balloon dilatation system is safe and performs as intended.
Shelf life	Accelerated aging tests as well as real time aging tests have demonstrated that the TubaVent has a shelf life of 3 years, if stored under the recommended conditions. The insertion device TubaInsert, has a shelf life of 5 years, the Tuba inflation devices a shelf life of 3 years.

Sterilization	Validation of the sterilization procedure and parameters has demonstrated that the TubaVent, TubaInsert and the Inflation device reach the sterility assurance level (SAL) of 10^{-6}.
Design validation	Design validation was performed in a human cadaver study.

8. Non-clinical Tests: Animal

N/A	No animal study was conducted.

9. Clinical Performance Data [**807.92(b)(2)**]

N/A	No clinical performance study was conducted for the TubaVent balloon dilatation system.

10. Summary non-clinical and clinical tests [807.92(b)(3)]

The TubaVent balloon dilatation system has met all acceptance criteria for attributes like dimensions, balloon burst pressure etc. Biocompatibility testing was performed in accordance to applicable parts of the the ISO 10993 standard. The TubaVent and all components of the system are biocompatible and do not cause sensitization or irritations. The sterilization process and parameters were validated in accordance with ISO 11135:2014. A sterility assurance level (SAL) of 10^{-6} is reached. Packaging shelf life has been proven for 3 years for the TubaVent and the inflation device (5 years for TubaInsert) via accelerated and/or real time aging. Thus, the performance test results demonstrate, that the TubaVent balloon dilatation system is as safe as the predicate device.

11. Conclusion

Based on the non-clinical performance data, it is concluded that the TubaVent balloon dilatation system is substantially equivalent to the predicate device under the Federal Food, Drug and Cosmetic Act.

Minor differences in design or material of the TubaVent balloon dilatation system compared to the predicate device do not raise any new questions with regard to the safety or performance or effectiveness of the medical device.

The TubaVent balloon dilatation system is identical to its predicate device with respect to the intended use and the indications for use. It uses the same fundamental scientific technology compared to the predicate device, as it has the same operating principle and the same basic design.

SPIGGLE & THEIS therefore believes that the TubaVent balloon dilatation system is as safe and effective and performs as the predicate device when used as instructed by knowledgeable and trained surgeons.

TubaVent balloon dilatation system is substantial equivalent to the legally marketed predicate device.