August 16, 2021

Medtronic Xomed, Inc.
Matthew Harmon
Principal Regulatory Affairs Specialist
6743 Southpoint Drive North
Jacksonville, Florida 32216

Re: K210841
Trade/Device Name: NuVent Eustachian Tube Dilation Balloon
Regulation Number: 21 CFR 874.4180
Regulation Name: Eustachian Tube Balloon Dilation System
Regulatory Class: Class II
Product Code: PNZ
Dated: July 20, 2021
Received: July 21, 2021

Dear Matthew Harmon:

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, 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)*
K210841

Device Name
NuVent Eustachian Tube Dilation Balloon

Indications for Use *(Describe)*
The NuVent Eustachian Tube Dilation Balloon is indicated for use in patients 18 years and older who need treatment for persistent Eustachian tube dysfunction.

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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510(k) Summary

K210841

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Contact: Matthew Harmon
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Date Prepared: August 12, 2021

Device Trade name: NuVent Eustachian Tube Dilation Balloon

Common Name: Eustachian Tube Balloon Dilation System

Classification Name: Eustachian Tube Balloon Device (21 CFR 874.4180)

Classification: Class II (21 CFR 874.4180)

Product Code: PNZ

Primary Predicate Device: XprESS ENT Dilation System K163509

Secondary Predicate Device: Aera®Eustachian Tube Balloon Dilation System K171761

Device Description:

The NuVent™ Eustachian Tube Dilation Balloon is composed of a sterile, single use balloon handpiece and stopcock valve. The balloon is used in conjunction with the NuVent™ inflator, which is packaged with extension tubing to connect the inflator to the stopcock valve. The NuVent™ Inflator was cleared as a part of the NuVent™ EM Sinus Balloon Dilation System, 510(k) cleared under K132297.

A pre-angled flexible balloon section promotes easy access and insertion into the Eustachian tube from the nasal opening with the aid of endoscopic guidance. An atraumatic tip at the distal end of the flexible balloon section is meant to reduce the potential for risk of injury to the Eustachian tube and surrounding tissues during insertion. The rigid shaft and handle extending to the flexible balloon section provides stability and tactile feedback when moving the balloon through the nasal passages and into the Eustachian tube canal.

Mounted near the distal end of the balloon handpiece is a flexible balloon section. Once the balloon section is advanced into the target Eustachian tube the 6mm diameter/16 mm long rigid balloon is inflated using the separate NuVent™ inflator, expanding the Eustachian tube canal tissue and cartilage.

Indications for Use:

The NuVent™ Eustachian Tube Dilation Balloon is indicated for use in patients 18 years and older who need treatment for persistent Eustachian tube dysfunction.

Technological Characteristics:

The NuVent™ device has the same intended use, same indications for use, same principle of operation, function, biocompatibility, and sterilization as well as similar design and materials to the primary predicate XprESS™ device and the secondary predicate Aera® device.

Please find a comparison of the subject NuVent™and the primary predicate XprESS™ device in Table 1, and a comparison of the subject NuVent™ and secondary predicate Aera® device in Table 2, below.

Table 1: Device Comparison – NuVent™ and XprESS™ Devices

Feature/ Attribute		NuVent™ Eustachian Tube Dilation Balloon Subject Device	XprESS™ ENT Dilation System K163509 Primary Predicate Device	Comparison
Product Code		PNZ	PNZ, LRC	Both have PNZ product code.
Regulations		21 CFR 874.4180	21 CFR 874.4180 21 CFR 874.4420	Both are subject to 21 CFR 874.4180.
Common Name		Eustachian Tube Balloon Dilation Device	Balloon Sinus Dilation System ; Eustachian Tube Balloon Dilation System	Both are Eustachian Tube Balloon Dilation Systems.
Description	**Handpiece**	The NuVent™ Eustachian Tube Dilation Balloon consists of an integrated polymer handle, stainless steel shaft, and flexible polymer balloon section with atraumatic polymer tip.	The XprESS ENT Dilation Balloons consist of an integrated polymer handle, stainless steel shaft and balloon section with a polymer balloon mounted on a polymer that slides over a stainless steel tube with a rounded metal tip.	Both provide an area for the surgeon to grip and manipulate the handpiece for delivery of the balloon into the nasal passage and Eustachian Tube canal.
	Rigid Shaft	Stainless steel 2.76 mm diameter x 95 mm long	Stainless steel 3.17 mm dia x ~100 mm long	Both contain rigid shafts to support manipulation of the devices for directing the tips to the entrance of the Eustachian Tube canal.
	Balloon	Non-compliant polymeric balloon, 6 mm diameter 16 mm long	Non-compliant polymeric balloon, 5 mm diameter x 8 mm long 5 x 20 mm 6 x 8 mm 6 x 20 mm 7 x 20 (LoProfile)	Both offer balloons that are 6 mm in diameter.
	Balloon Section	Flexible polymer tube with internal shaping wire	Stainless steel tube	Both have a balloon section that is bent at an angle meant to support insertion of the balloon into the Eustachian Tube canal. The Stryker device balloon sections are rigid and do not have flexibility.

Feature/ Attribute		NuVent™ Eustachian Tube Dilation Balloon Subject Device	XprESS™ ENT Dilation System K163509 Primary Predicate Device	Comparison
	Balloon Tip	Rounded 2.6 mm diameter polymer	Rounded 1.75mm diameter stainless steel (LoProfile) Rounded 1.50 mm diameter stainless steel (Ultra)	Both systems have rounded tips. The Medtronic balloon system is larger and polymeric.
	Insertion Method	The flexible polymer balloon section is angled to promote insertion of the polymer balloon section into the ET canal and the balloon section is inserted into the ET canal.	The rigid stainless steel balloon section is bent to the ET angle with a provided bending tool angled to promote insertion into the ET canal and the balloon section is inserted into the ET canal and the polymeric balloon is advanced into the ET canal over the top of the inserted SS balloon section.	Both devices provide a means for inserting the flexible balloon sections into the Eustachian Tube canal by including an angle that mimics the Eustachian Tube canal and both systems are inserted manually as a unitized handpiece.
	Insertion Marker	Blue band at the proximal end of the balloon 30mm from the tip visible under direct endoscopic visualization provides recognition of the depth of balloon insertion in the ET canal aiding in positioning the handpiece.	Markings on SS balloon section at 10 and 20 mm from tip.	Both balloon sections have markings on the balloon section to provide visual recognition of the depth of insertion.
	Inflator	The balloon handpiece is meant to be used in conjunction only with the Medtronic NuVent™ inflator to provide the pressure for the handpiece balloon. The inflator limits the pressure delivered.	The balloon handpiece is meant to be used in conjunction only with the Entellus Inflation Syringe which limits inflation pressure.	Both systems have inflators that readily connect to the handpiece with Luer fittings and provide pressure during the procedure.
Intended Use		To dilate the Eustachian tube canal.	To remodel or recreate the sinus outflow tract and dilate the Eustachian tube by transnasal balloon dilation.	Both devices are intended to dilate the Eustachian Tube canal.
Indications for Use		The NuVent Eustachian Tube Dilation Balloon is indicated for use in patients 18 years and older who need treatment for persistent Eustachian tube dysfunction.	To dilate the cartilaginous portion of the Eustachian tube for treating persistent Eustachian tube dysfunction in patients 18 years and older using a transnasal approach.	Both devices are indicated to treat persistent Eustachian Tube dysfunction in patients 18 years and older.
Predicate Device		Acclarent Aera® – K171761 XprESS ENT Dilation System – K163509	XprESS Multi-Sinus Dilation System (K152434) Acclarent Aera® (DEN150056)	N/A
Contraindications		The NuVent™ Eustachian Tube Dilation Balloon is contraindicated for use in a Eustachian tube with an ipsilateral carotid artery that is dehiscent into the Eustachian Tube lumen or history or ipsilateral patulous Eustachian tube.	The XprESS device does include warnings against using XprESS to dilate Eustachian tubes in patients with a history of patulous Eustachian tubes, to review appropriate radiographic imaging prior to treatment, and not to use the device to treat patients with evidence of internal carotid artery dehiscence.	Both devices are not intended to be used in patients who have patulous Eustachian Tubes or in patients with evidence of internal carotid artery dehiscence.
Contact Time		Limited (≤ 24 hours)	Limited (≤ 24 hours)	Identical
Sterility		Ethylene Oxide	Ethylene Oxide	Identical
Biocompatibility		ISO 10993-1	ISO 10993-1	Identical

Table 2: Device Comparison – NuVent™ and Aera® Devices

Feature/ Attribute		NuVent™ Eustachian Tube Dilation Balloon Subject Device	Aera® Eustachian Tube Balloon Dilation System K171761 Secondary Predicate Device	Comparison
Product Code		PNZ	PNZ	Identical
Regulations		21 CFR 874.4180	21 CFR 874.4180	Identical
Common Name		Eustachian Tube Balloon Dilation Device	Eustachian Tube Balloon Dilation Device	Identical
Description	**Handpiece**	The NuVent™ Eustachian Tube Dilation Balloon consists of an integrated polymer handle, stainless steel shaft, and flexible polymer balloon section with an atraumatic polymer tip.	The ACCLARENT AERA® Eustachian Tube Dilation Balloon consists of a rigid Guide Catheter and a flexible polymer Balloon Catheter with an atraumatic polymer tip.	Both consist of a rigid shaft and flexible balloon section with an atraumatic polymer tip. They differ in that the NuVent™ device is a single handpiece, while the Aera™ device uses as separate guide catheter and balloon catheter.
	Rigid Shaft	Stainless steel 2.76 mm diameter x 95 mm long	Stainless steel & rigid polymer end 3.83 mm dia x 83 mm long SS and 17 mm long polymer = ~100 mm	Both contain rigid shafts to support manipulation of the devices for directing the tips to the entrance of the Eustachian Tube canal.
	Balloon	Non-compliant polymeric balloon, 6 mm diameter 16 mm long	Non-compliant polymeric balloon, 6 mm diameter x 16 mm long	Identical
	Balloon Section	Flexible polymer tube with internal shaping wire	Flexible polymer tube	Both have flexible balloon sections with adequate stiffness to support insertion of the balloon into the Eustachian Tube canal.
	Balloon Tip	Rounded 2.6 mm diameter polymer	Rounded 2.4 mm diameter polymer	Both devices have bulbous, atraumatic, and polymeric tips.
	Insertion Method	The flexible polymer balloon section is angled to promote insertion of the polymer balloon section into the ET canal and the balloon section is inserted into the ET canal.	The flexible polymer balloon catheter is advanced through the angled tip of the guide catheter, inserting the balloon into the ET canal.	Both devices provide a means for inserting the flexible balloon sections into the Eustachian Tube canal by including an angle that mimics the Eustachian Tube canal. The Aera device does so by following the guide catheter and the Medtronic device by inclusion of an angled balloon section of a unitized handpiece.
	Insertion Marker	Blue band at the proximal end of the balloon 30mm from the tip visible under direct endoscopic visualization provides recognition of the depth of balloon insertion in the ET canal aiding in positioning the handpiece.	No visual markers present to estimate depth of Eustachian tube insertion. The device has a marker on the balloon catheter to indicate when the balloon section of the balloon catheter is extended past the distal end of the guide catheter.	Both balloon sections are 30 mm long. The NuVent™ balloon includes a visual marker to provide easy recognition of the end of the flexible balloon and recognition of the depth of insertion. The Aera device also has a visual marker, but it does not indicate the depth of balloon insertion.
	Inflator	The balloon handpiece is meant to be used in conjunction only with the Medtronic NuVent™ inflator to provide the pressure for the handpiece balloon. The inflator limits the pressure delivered.	The balloon handpiece is compatible with either the Acclarent® Balloon Inflation Device or Acclarent® SE Inflation Device and is instructed to not exceed 12 atm pressure.	Both systems have inflators that readily connect to the handpiece with Luer fittings and provide pressure and a way to maintain the pressure during the procedure.
Intended Use		To dilate the Eustachian tube canal.	To dilate the Eustachian tube canal.	Identical
Indications for Use		The NuVent Eustachian Tube Dilation Balloon is indicated	The Acclarent Aera® Eustachian Tube Balloon Dilation System is intended to	Identical

Feature/ Attribute	NuVent™ Eustachian Tube Dilation Balloon Subject Device	Aera® Eustachian Tube Balloon Dilation System K171761 Secondary Predicate Device	Comparison
	for use in patients 18 years and older who need treatment for persistent Eustachian tube dysfunction.	dilate the Eustachian tube for treatment of persistent Eustachian tube dysfunction in patients 18 years and older.	
Predicate Device	Acclarent Aera® – K171761 XprESS ENT Dilation System – K163509	Acclarent Aera® (DEN150056) Entellus XprESS ENT Dilation System (K163509)	N/A
Contraindications	The NuVent™ Eustachian Tube Dilation Balloon is contraindicated for use in a Eustachian tube with an ipsilateral carotid artery that is dehiscent into the Eustachian Tube lumen or history or ipsilateral patulous Eustachian tube.	The Acclarent Aera® Eustachian Tube Balloon Dilation System is contraindicated for use in a Eustachian tube with an ipsilateral carotid artery that is dehiscent into the ET lumen or history of ipsilateral patulous Eustachian tube.	Identical
Contact Time	Limited (≤ 24 hours)	Limited (≤ 24 hours)	Identical
Sterility	Ethylene Oxide	Ethylene Oxide	Identical
Biocompatibility	ISO 10993-1	ISO 10993-1	Identical

Substantial Equivalence:

The NuVent™ Eustachian Tube Dilation Balloon has the same intended use, indications for use, and similar scientific technology as the primary predicate XprESS device (K163509) and the secondary predicate Aera® device (K171761). In support of this determination Medtronic conducted non-clinical tests to demonstrate compliance with the special controls applicable to this device, as set out in 21 CFR 874.4180, including tensile and flexural testing, durability testing, inflation and deflation testing, verification testing of the safety features on both the NuVent device and the NuVent inflator, biocompatibility testing, and sterility testing. The NuVent device met all acceptance criteria for this testing.

Medtronic conducted usability and validation testing on the NuVent device. In addition, to show equivalence to the predicate devices, Medtronic conducted comparison testing between the subject NuVent, primary predicate XprESS, and secondary predicate Aera to assess balloon characteristics by performing flexibility, torsional, and axial rigidity tests to demonstrate the NuVent device is as safe and effective as the primary and secondary predicates.

A comparison of the devices' dimensions, materials, design, power source, insertion methods, and instructions for use, as shown in **Table 1** and **Table 2**, above, does not indicate any differences in the potential risks for each device and does not raise different questions of safety or effectiveness than the predicate Aera and XprESS devices. Therefore, the NuVent™ Eustachian Tube Dilation Balloon is substantially equivalent to the primary predicate XprESS device and the secondary predicate Aera device.

Biocompatibility:

Biocompatibility testing was performed using ISO 10993 Biological Evaluation of Medical Devices and FDA guidance document "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,'" issued June 16, 2016. The

NuVent™ Eustachian Tube Dilation Balloon complies with the biocompatibility requirements for its intended use.

Sterilization:

Sterilization is accomplished via ethylene oxide to deliver a minimum sterility assurance level (SAL) of 10^{-6}. The sterilization method was validated in compliance to:

- ISO 11135:2014 – Sterilization of Health Care Products – Ethylene Oxide – Requirements for development, validation, and routine control of a sterilization process for medical devices.
- ISO 11138-2: 2017 – Sterilization of health care products: Biological Indicators – Part 2: Biological indicators for ethylene oxide sterilization processes
- ISO 11737-1:2018 – Sterilization of Health Care Products - Microbiological Methods – Part 1: Determination of the Population of Microorganisms on Product
- ISO 11737-2: 2019 - Sterilization of Health Care Products - Microbiological Methods – Part 2: Tests of sterility performed in the definition, validation, and maintenance of a sterilization process.

Performance Testing:

Performance testing consisted of testing to support the substantial equivalence of the NuVent™ device to the predicate Aera® and XprESS™ devices, and to support the safety and effectiveness of the NuVent™ device. All testing was conducted on the sterile final product, and followed the appropriate standards and guidance documents, with appropriate modifications following risk assessment. Testing plans were based upon FDA guidance documents and international standards. Testing was performed on baseline (non-aged) and aged products.

Testing included:

- Wire dislodgement
- Balloon inflation
- Balloon deflation
- Stopcock holding pressure without leaking
- Pressure indicator button functionality
- System does not leak or burst under use conditions in cyclic testing
- Handpiece does not leak at the rated burst pressure in cyclic testing
- Tensile strength of balloon, balloon bonds and tip
- Torsional testing of balloon system
- Usability testing, including simulated use
- Flexibility testing comparing the flexibility and rigidity of the subject and predicate devices under the conditions of axial, angular, and torsional loading of the balloon sections.

All samples passed testing and met acceptance criteria. This testing demonstrates that the subject NuVent™ device is as safe, as effective, and performs as well as the predicate Aera® and XprESS™ devices.

Shelf Life Testing:

Shelf life testing was performed on the sterile final product and its packaging according to the applicable standards and guidance documents. The sterile final product and packaging were subjected to accelerated aging per ASTM F1980 – 2016. Real-time aging for the accelerated aging equivalent time is ongoing.

All samples passed testing and met the acceptance criteria of the design inputs for the device and packaging system following accelerated aging.

Conclusion:

Utilizing FDA's Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)s" issued on September 13, 2019, a comparison of key characteristics demonstrates that the proposed device NuVent™ Eustachian Tube Dilation Balloon is substantially equivalent to the predicate device(s) in terms of performance characteristics. The NuVent™ Eustachian Tube Dilation Balloon is as safe, as effective, and performs as well as the predicate device(s).