August 27, 2020

Acclarent Inc.
David Locke
Manager, Regulatory Affairs
31 Technology Dr., Suite 200
Irvine, California 92618

Re: K201115
Trade/Device Name: Next Generation Balloon Dilation System
Regulation Number: 21 CFR 874.4180
Regulation Name: Eustachian Tube Balloon Dilation System
Regulatory Class: Class II
Product Code: PNZ, PGW, LRC
Dated: July 25, 2020
Received: July 28, 2020

Dear David Locke:

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,

for Malvina B. Eydelman, M.D.
Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201115

Device Name
Next Generation Balloon Dilation System

Indications for Use *(Describe)*

The NGB Balloon Dilation System is intended to provide a means to access the sinus space within and across nasal and sinus structures; dilate the sinus ostia and spaces associated with the paranasal sinus cavities for diagnostic and therapeutic procedures; irrigate from within a target sinus; suction throughout therapeutic procedures and to facilitate diagnostic procedures.
For children aged 17 and under, the NGB Balloon Dilation System is intended to provide a means to access the sinus space within and across nasal and sinus structures; dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures; irrigate from within the maxillary sinus; suction throughout therapeutic procedures and to facilitate diagnostic procedures.
The NGB Balloon Dilation System is intended to dilate the cartilaginous Eustachian tube for treatment of persistent Eustachian tube dysfunction in patients ages 18 and older.
The NGB Balloon Dilation System with the navigation guidewire may be utilized in conjunction with the TruDi™ Navigation System, to help direct access to nasal and paranasal spaces, and to confirm placement in the targeted anatomy. NGB may be utilized in conjunction with the TruDi™ NAV Wire to confirm placement of the balloon in the Eustachian tube.
The NGB Balloon Dilation System with the illumination guidewire may be utilized to illuminate within and provide transcutaneous illumination across nasal and sinus structures.

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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K201115 - 510(K) SUMMARY

[807.92(a)(1)] Submitter Information

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Acclarent Inc.
Phone: 419-233-2611

Date Summary Prepared: Aug 26, 2020

[807.92(a)(2)] Name of Device

Device Trade Name: Next Generation Balloon - Balloon Dilation System
Device Common Name: Next Generation Balloon Dilation System
Classification Name: Eustachian tube balloon dilation system (21 CFR 874.4180)

Device Classification: Class II

Product Code: PNZ
Secondary Codes: PGW, LRC
Review Panel: Ear, Nose and Throat

[807.92(a)(3)] Legally Marketed Devices

Primary Predicate Device: Acclarent AERA® Eustachian Tube Balloon Dilation System (K171761)

Secondary Predicate Devices: Relieva SpinPlus® Nav Balloon Sinuplasty System (K171687)
Relieva SpinPlus® Balloon Sinuplasty System (K143541)

Reference Device: Acclarent TruDi NAV Wire (K190532)

[807.92(a)(4)] Device Description

Device Description:

The Next Generation Balloon Dilation System (NGB) is an integrated balloon sinuplasty (BSP) and Eustachian tube (ET) dilation device, that will be available in light fiber and navigation guidewire configurations for compatibility with illumination and navigation technology. The system includes a handle with several integrated features to allow for single-handed use. The adjustable gripping feature allows for ergonomic handling. The directable guide tip enables access (i.e. manipulating/separating/dividing tissue) and placement near the targeted anatomy. There are four preset approximate positions: Sphenoid (straight), Eustachian tube (55˚), Frontal (70˚), Maxillary (110˚). The directable guide knob allows for positioning of the balloon tip towards the target anatomy. The wire slider and spinner are used to advance, retract, and rotate the guidewire. The balloon slider is used advance and retract the balloon. The Next Generation Balloon Dilation System also allows for suction and irrigation in and around the target anatomy.

[807.92(a)(5)] Intended Use and Predicate Device Comparison

Indications for Use:

The NGB Balloon Dilation System is intended to provide a means to access the sinus space within and across nasal and sinus structures; dilate the sinus ostia and spaces associated with the paranasal sinus cavities for diagnostic and therapeutic procedures; irrigate from within a target sinus; suction throughout therapeutic procedures and to facilitate diagnostic procedures.

For children aged 17 and under, the NGB Balloon Dilation System is intended to provide a means to access the sinus space within and across nasal and sinus structures; dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures; irrigate from within the maxillary sinus; suction throughout therapeutic procedures and to facilitate diagnostic procedures.

The NGB Balloon Dilation System is intended to dilate the cartilaginous Eustachian tube for treatment of persistent Eustachian tube dysfunction in patients ages 18 and older.

The NGB Balloon Dilation System with the navigation guidewire may be utilized in conjunction with the TruDi™ Navigation System, to help direct access to nasal and paranasal spaces, and to confirm placement in the targeted anatomy. NGB may be utilized in conjunction with the TruDi™ NAV Wire to confirm placement of the balloon in the Eustachian tube.

The NGB Balloon Dilation System with the illumination guidewire may be utilized to illuminate within and provide transcutaneous illumination across nasal and sinus structures.

[807.92(a)(6)] Technical Characteristics

Technological Characteristics:	The Next Generation Balloon Dilation System combines Sinuplasty and Eustachian Tube Dilation into a single handheld device. The device also allows for the use of the Acclarent TruDi™ NAV Wire for real-time tracking within nasal and Eustachian tube anatomy as well as an illumination wire for transcutaneous illumination across, nasal and sinus structures.
Non-clinical Performance Data:	The Next Generation Balloon was tested to ensure that it functions in accordance with the device design specifications related to substantial equivalence in terms of device safety and effectiveness. The following nonclinical tests were performed: 1. Bench testing has been performed and met all acceptance criteria for attributes such as simulated use testing, dimensional attributes, cycle fatigue, balloon burst, bond separation, irrigation flow rate and device accuracy. Moreover, testing also showed that the Next Generation Balloon Dilation System is biocompatible. 2. The sterilization process has been validated per AAMI/ANSI/ISO 11135-1: 2007 and demonstrated a sterility assurance level of 10-6. The method used for sterilization validation is the overkill (half-cycle approach) in a fixed chamber. Ethylene oxide residuals have been tested and meet ISO 10993-7:2008 requirements. The subject device is not tested nor labeled as “non-pyrogenic”. 3. Packaging shelf life has been established to be 3 months per ASTM F1980-07. 4. Mechanical testing was performed, including tensile and flexural testing of catheter joints and materials. 5. Durability testing was performed, including fatigue and burst pressure testing of the balloon materials and components. 6. Inflation and deflation characterization testing was performed, including time and pressure measurements, and leak testing of the balloon. 7. Verification testing of safety features built into the device was performed, including the characterization of catheter geometries and distal tip insertion limitation mechanisms. 8. Simulated use testing in a clinically relevant model demonstrated the reliability of the device to remain mechanically functional throughout the anticipated conditions of use, and that the design features limit access to only the cartilaginous portion of the Eustachian tube. 9. The Next Generation Balloon Dilation System passed all tests in accordance with appropriate test criteria and standards, and the modified device did not raise new questions of safety or effectiveness.

Clinical Data:	Clinical data was not necessary to determine that the subject Next Generation Balloon Dilation System performs as intended.
Conclusion:	The modified Next Generation Balloon Dilation System device is substantially equivalent to the currently cleared Acclarent AERA® Eustachian Tube Balloon Dilation System and the secondary predicate devices based on the completion of non-clinical bench testing as well as similar principles of design, operation and indications for use.

Substantial Equivalence Table

Attribute	**Primary Predicate Device:** ACCLARENT AERA® Eustachian Tube Balloon Dilation System	**Secondary Predicate Device:** RELIEVA SPINPLUS® NAV Balloon Sinuplasty System	**Secondary Predicate Device:** RELIEVA SPINPLUS® Balloon Sinuplasty System	**Reference Device:** TruDi™ NAV Wire®	**Subject Device:** Next Generation Balloon Dilation System	**Substantial Equivalence Rationale**
510(k) number	K171761	K171687	K143541	K190532	K201115	N/A
Manufacturer	Acclarent	Acclarent	Acclarent	Acclarent	Acclarent	N/A
Trade Name	ACCLARENT AERA® Eustachian Balloon Dilation System	RELIEVA SPINPLUS® NAV Balloon Sinuplasty System	Relieva SpinPlus Balloon Sinuplasty System	TruDi™ NAV Wire	Next Generation Balloon Dilation System	N/A
Common Name	Eustachian Tube Balloon Dilation Device	Sinus Dilation System	Sinus Dilation System	Image Guided Surgery System	Eustachian Tube Balloon Dilation Device	N/A
Class	II	I	I	II	II	Same as the higher classification devices

Attribute	**Primary Predicate Device:** ACCLARENT AERA® Eustachian Tube Balloon Dilation System	**Secondary Predicate Device:** RELIEVA SPINPLUS® NAV Balloon Sinuplasty System	**Secondary Predicate Device:** RELIEVA SPINPLUS® Balloon Sinuplasty System	**Reference Device:** TruDi™ NAV Wire®	**Subject Device:** Next Generation Balloon Dilation System	**Substantial Equivalence Rationale**
Classification Product Code	PNZ	LRC	LRC	PGW	PNZ	Same as primary predicate device
Subsequent Product Code	N/A	PGW	N/A	N/A	PGW, LRC	N/A
Classification Section	874.4180	874.4420	874.4420	882.4560	874.4180	Same as primary predicate device

Indications for Use	The ACCLARENT AERA® Eustachian Tube Balloon Dilation System is intended to dilate the Eustachian tube for treatment of persistent Eustachian tube dysfunction in patients ages 18 and older.	The RELIEVA SPINPLUS® NAV Balloon Sinuplasty System is intended to provide a means to access the sinus space, within and across nasal and sinus structures; dilate the sinus ostia and spaces associated with the paranasal sinus cavities for diagnostic and therapeutic procedures; and irrigate from within a target sinus for therapeutic procedures and to facilitate diagnostic procedures. For children aged 17 and under, the RELIEVA SPINPLUS® NAV Balloon Sinuplasty System is intended to provide a means to access the sinus space, within and across nasal and sinus structures; dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures; and irrigate from within the maxillary sinus for therapeutic procedures and to facilitate diagnostic procedures. The RELIEVA SPINPLUS® NAV Balloon Sinuplasty System may be	The RELIEVA SPINPLUS™ Balloon Sinuplasty System is intended to: provide a means to access the sinus space and illuminate within and transilluminate across nasal and sinus structures; dilate the sinus ostia and spaces associated with the paranasal sinus cavities for diagnostic and therapeutic procedures; and irrigate from within a target sinus for therapeutic procedures and to facilitate diagnostic procedures. For children aged 17 and under, the RELIEVA SPINPLUS™ Balloon Sinuplasty System is intended to: provide a means to access the sinus space and illuminate within and transilluminate across nasal and sinus structures; dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures; and irrigate from within the maxillary sinus	The TruDi™ NAV Wire is intended for use as an electromagnetically navigable guidewire to provide access and confirmation of placement in the patient anatomy. The device is intended for use during ENT procedures where reference to a rigid anatomical structure can be identified relative to a CT-based model of the anatomy.	The NGB Balloon Dilation System is intended to provide a means to access the sinus space within and across nasal and sinus structures; dilate the sinus ostia and spaces associated with the paranasal sinus cavities; irrigate from within a target sinus; suction throughout therapeutic procedures and to facilitate diagnostic procedures. For children aged 17 and under, the NGB Balloon Dilation System is intended to provide a means to access the sinus space within and across nasal and sinus structures; dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures; irrigate from within the maxillary sinus; suction throughout therapeutic procedures and to facilitate diagnostic procedures. The NGB Balloon Dilation System is intended to dilate	The IFU and Indications of the subject Next Generation Balloon Dilation System is aligned with the predicate devices. The merging of technologies within the indications does not bring about any new concerns with respect to substantial equivalence, and the safety and effectiveness of the subject device is supported by completed device testing.

		utilized in conjunction with the ACCLARENT® ENT Navigation System, to provide access to nasal and sinus spaces, and to confirm placement in the accessed anatomy."	for therapeutic procedures and to facilitate diagnostic procedures.		the cartilaginous Eustachian tube for treatment of persistent Eustachian tube dysfunction in patients ages 18 and older. The NGB Balloon Dilation System with the navigation guidewire may be utilized in conjunction with the TruDi™ Navigation System, to help direct access to nasal and paranasal spaces, and to confirm placement in the targeted anatomy. NGB may be utilized in conjunction with the TruDi™ NAV Wire to confirm placement of the balloon in the Eustachian tube. The NGB Balloon Dilation System with the illumination guidewire may be utilized to illuminate within and provide transcutaneous illumination across nasal and sinus structures. .	

Attribute	**Primary Predicate Device:** ACCLARENT AERA® Eustachian Tube Balloon Dilation System	**Secondary Predicate Device:** RELIEVA SPINPLUS® NAV Balloon Sinuplasty System	**Secondary Predicate Device:** RELIEVA SPINPLUS® Balloon Sinuplasty System	**Reference Device:** TruDi™ NAV Wire® Sinus Navigation Guidewire	**Subject Device:** Next Generation Balloon Dilation System	**Substantial Equivalence Rationale**
Sterilization	EtO	EtO	EtO	EtO	EtO	Same
Packaging	PETG thermoformed tray in Tyvek/Nylon pouch	PETG thermoformed tray in Tyvek/Nylon pouch	PETG thermoformed tray in Tyvek/Nylon pouch	Backer-card in Tyvek/Nylon pouch	PETG thermoformed tray in Tyvek/Nylon pouch	Same
Single Use	Yes	Yes	Yes	Yes	Yes	Same
Patient Contact	Direct	Direct	Direct	Direct	Direct	Same
Labeled as Non-Pyrogenic?	No	No	No	No	No	Same
Technological Characteristics	The ACCLARENT AERA® Eustachian Tube Balloon Dilation System is a device that allows for dilation of the cartilaginous	The RELIEVA SPINPLUS® NAV Balloon Sinuplasty System combines a	The RELIEVA SPINPLUS® Balloon Sinuplasty System combines a Sinus Guide	The TruDi™ NAV Wire utilizes electromagnetic image-guided sinus surgery	The NEXT GENERATION BALLOON DILATION SYSTEM combines	The technological characteristics have been tested through non-clinical testing and they do not

	portion of the Eustachian tube. Eustachian tube dilation is achieved via a noncompliant balloon located on the distal end of the device.	Sinus Guide Catheter and Handle Assembly (integrated with Sinus Balloon Catheter, Sinus Irrigation and Sinus Navigation System) into a single device. The device is connected to the Acclarent ENT Navigation System to provide location information via EM navigation relative to a pre-loaded scan.	Catheter and Handle Assembly (integrated with Sinus Balloon Catheter, Sinus Irrigation and Sinus Illumination System) into a single device. The device is connected to any standard light source via accessory light cable and adapter.	and is used in conjunction with a compatible surgical navigation system which consists of computer-aided software, CT-imaging, patient tracker, registration probe, and various instruments used in sinus surgery. TruDi® NAV Wire provides real-time tracking at the distal tip of the guidewire in the nasal anatomy.	Sinuplasty and Eustachian Tube Dilation into a single handheld device. The device also allows for the use of the Acclarent TruDi Nav Wire for real-time tracking within nasal and Eustachian tube anatomy as well as an illumination wire for transcutaneous illumination across, nasal and sinus structures.	impact substantial equivalence. Moreover, the minor technological differences do not raise any new concerns with respect to safety and effectiveness.
Material	PTFE, Polycarbonate, Nylon, Pebax, Grilamid Ely, Barium, Pebax, Blue Nylon, Barium, Marabu TPU ink, Stainless Steel,	Pebax, PET, Loctite, Pad printing, Stainless steel, PEEK, Polycarbonate, Nylon, PTFE, Polyester,	Pebax, PET, Loctite, Pad printing, Stainless steel, PEEK, Polycarbonate, Nylon, PTFE, Polyester, Silicone rubber,	Polycarbonate Pebax Ethyl Cyanoacrylate Adhesive, Silver Plated Copper, PTFE, Silver	Pebax, PET, Loctite, Pad printing, Stainless steel, PEEK, Polycarbonate, Nylon, PTFE, Polyester, Silicone	The materials used are those commonly used in medical devices and have been tested via

	Polyolefin, Loctite 4014, Loctite 4011, Dymax 204CTH, Loctite 745, Platinum, 10% Iridium, Loctite 408, Loctite 7451, Dymax 1191	Silicone rubber, Polypropylene, Silicone, Tygon, Parylene, Polyurethane, Silver Plated Copper, Antioxidant Nickel-Iron-Molybdenum Alloy, fiberglass insulation, RoHS-compliant PCB Assembly, Adhesive Silver Plated Copper	Polypropylene, Silicone, Tygon, Parylene, Polyurethane	Filled Polycarbonate/ABS RoHS-compliant PCB Assembly Polypropylene, Hydrocarbon Resin, Styrene-Butadiene Polymer, Paraffin Wax, Polyethylene, Antioxidant, Nickel-Iron-Molybdenum Alloy, Stainless Steel, Silicone	rubber, Polypropylene, Silicone, Tygon, Parylene, Polyurethane, Silver Plated Copper, Antioxidant Nickel-Iron-Molybdenum Alloy, fiberglass insulation, RoHS-compliant PCB Assembly, Adhesive Silver Plated Copper SE508 Nitinol	biocompatibility. The materials use in the subject device are the same as the predicate devices. There are no new concerns with respect to safety and effectiveness and the materials used in the subject device are substantially equivalent to the predicate devices.
Balloon Material	PET	Nylon	PET	N/A	Nylon	The balloon material is equivalent to that of the currently marketed primary predicate device.
Balloon Length	16 mm	16 mm	16 mm	N/A	16 mm	Same
Guidewire Diameter	N/A	0.035 inches	N/A	0.035 inches	0.035 inches	Same as compared to applicable devices
Deflation Time	≤5 seconds	≤5 seconds	≤5 seconds	N/A	≤5 seconds	Same

Maximum Inflation Pressure	12 ATM	12 ATM	12 ATM	N/A	12 ATM	Same
Flexible Balloon Catheter	Yes	Yes	Yes	N/A	Yes	Same
Balloon Radiopaque Marker Bands	No	No	No	N/A	No	Same
Suction Incorporated	No	Yes	Yes	No	Yes	Same as compared to applicable devices
Irrigation Incorporated	No	Yes	Yes	No	Yes	Same as compared to applicable devices
Balloon Slide Mechanism	No	Yes	Yes	No	Yes	Same as compared to applicable devices
Indicated for Children	Yes - Eustachian tube dilation for 18 years old and greater	Yes, maxillary sinus for children 17 and under	Yes, maxillary sinus for children 17 and under	Yes, maxillary sinus for children 17 and under	Yes, maxillary sinus for children 17 and under Yes – Eustachian tube dilation for 18 years old and greater	Same: Sinus Dilation - maxillary sinus for children 17 and under. Eustachian Tube Dilation - 18 years and greater.

Compatible with ACCLARENT ® ENT Navigation System	No	Yes	No	Yes	Yes	Same with respect to those devices that connect to the TruDi Navigation System.