DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 24, 2016

Acclarent, Inc.
Mr. James Patrick Garvey II
Associate Director, Regulatory Affairs
33 Technology Drive
Irvine, CA 92618

Re: K161698
Trade/Device Name: Acclarent Relieva Ultirra® Nav Sinus Balloon Catheter
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose, and Throat Manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: September 21, 2016
Received: September 22, 2016

Dear Mr. Garvey:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161698

Device Name

Relieva UltirraNav™ Sinus Balloon Catheter

Indications for Use *(Describe)*

The Relieva UltirraNav™ Sinus Balloon Catheter is an instrument intended to dilate the sinus ostia and spaces within the maxillary, frontal, and sphenoid paranasal sinus cavities for diagnostic and therapeutic procedures.

For children aged 17 and under, the balloon catheter system is intended to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures.

The Relieva UltirraNav™ Sinus Balloon Catheter may be utilized in conjunction with the NavWire Sinus Navigation Guidewire and CARTO® ENT System to to confirm placement in the accessed anatomy relative to pre-acquired CT images.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Traditional 510(k) Summary – Relieva Ultirra® Nav Sinus Balloon Catheter

[807.92(a)(1)] Submitter Information

Sponsor/Submitter:	Acclarent, Inc. 33 Technology Drive Irvine, CA 92618
Contact Person:	Patrick Garvey Associate Director, Regulatory Affairs Email: pgarvey@its.jnj.com Tel: 949-789-8505
Date Summary Prepared:	September 21, 2016

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

Device Trade Name:	Relieva Ultirra® Nav Sinus Balloon Catheter
Common Name:	Sinus Balloon Catheter
Device Classification:	Class I
Regulation Number:	21 CFR 874.4420
Classification Name:	Ear, Nose, and Throat Manual Surgical Instrument (21 CFR 874.4420)
Product Code:	LRC

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

Predicate Devices:	Relieva Solo Elite™ Sinus Balloon Catheter (K111254) Medtronic EM Dilation Tool (K132297)

[807.92(a)(4)] Device Description

Device Description:	The Relieva Ultirra® Nav Sinus Balloon Catheter is a flexible catheter that is intended to dilate sinus ostia. The shaft allows for inflation of the sinus balloon and permits the passage of an electromagnetic navigable sinus guidewire or sinus illumination system to facilitate access to the target sinus ostia. A hypotube is incorporated on the proximal end to provide rigidity during insertion through a sinus guide catheter.

[807.92(a)(5)] Intended Use	
Indications for Use:	The Relieva Ultirra® Nav Sinus Balloon Catheter is an instrument intended to dilate the sinus ostia and spaces within the maxillary, frontal, and sphenoid paranasal sinus cavities for diagnostic and therapeutic procedures. For children aged 17 and under, the balloon catheter system is intended to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures. The Relieva Ultirra® Nav Sinus Balloon Catheter may be utilized in conjunction with the Acclarent NavWire™ Sinus Navigation Guidewire and CARTO® ENT System to provide access to nasal and sinus spaces, and to confirm placement in the accessed anatomy.
Difference in Indications from Predicate Device	The difference in indications for use between the subject and predicate devices is supported is presented in Table 1 of this summary.

[807.92(a)(6)] Technical Characteristics	
Technological Characteristics:	The Relieva Ultirra® Nav Sinus Balloon Catheter is a device that allows for dilation of sinus ostia with the added capability to be utilized with the CARTO®ENT Navigation System. Sinus dilation is achieved via a non-compliant balloon located on the distal end of the device. See Table 1 for a comparison of the technological characteristics between the Relieva Ultirra® Nav Sinus Balloon Catheter and the predicate devices.

Table 1: Comparison of Technological Characteristics between the Relieva Ultirra® Nav Sinus Balloon Catheter and predicate devices.

Attribute	**Primary Predicate Device:** Relieva Solo Elite™ Sinus Balloon Catheter	**Secondary Predicate Device:** Medtronic EM Dilation Tool	**Subject Device:** Relieva Ultirra® Nav Sinus Balloon Catheter
510(k) Number	K111254	K132297	K161698
Manufacturer	Acclarent, Inc.	Medtronic Xomed, Inc.	Acclarent, Inc.
Common Name	Sinus Balloon Dilation System	EM Sinus Dilation System	Sinus Balloon Dilation System
Class	I	I	I
Product Code	LRC	LRC	LRC
Classification Section	21 CFR 874.4420	21 CFR 874.4420	21 CFR 874.4420
Indicated for Children	Yes	No	Yes
Single Patient Use	Yes	Yes	Yes
Direct Patient Contact	Yes	Yes	Yes
Labeled as Non-Pyrogenic?	No	No	No
Balloon Diameter	3.5mm, 6mm, 7mm	5mm, 6mm, 7mm	5mm
Balloon Length	16mm	Frontal = 17mm Maxillary = 7mm Sphenoid = 17mm	16mm
Working Length	245 mm	Unknown	245 mm
Maximum Inflation Pressure	12 ATM	Unknown	12 ATM
Flexible Shaft	Yes	No	Yes

Attribute	**Primary Predicate Device:** Relieva Solo Elite™ Sinus Balloon Catheter	**Secondary Predicate Device:** Medtronic EM Dilation Tool	**Subject Device:** Relieva Ultirra® Nav Sinus Balloon Catheter
Indications for Use	The *Relieva Ultirra*® Sinus Balloon Catheter is an instrument intended to dilate sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures. It is also intended to irrigate from within a target sinus for therapeutic procedures and to facilitate diagnostic procedures. For children aged 17 and under, the balloon catheter system is intended to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures. It is also intended to irrigate from within a target sinus for therapeutic procedures and to facilitate diagnostic procedures.	The EM Sinus Dilation System is intended for use in sinus procedures when surgical navigation or image-guided surgery may be necessary to locate and move tissue, bone, or cartilaginous tissue surrounding the drainage pathways of the frontal, maxillary, sphenoid sinuses. The EM Dilation system is used in conjunction with the Medtronic Computer-assisted surgery system. The Medtronic computer-assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT or MR based model, or digitized landmarks of the anatomy. The system and its associated applications should be used only as an adjunct for surgical guidance. They do not replace the surgeon's knowledge, expertise, or judgment.	The Relieva Ultirra® Nav Sinus Balloon Catheter is an instrument intended to dilate the sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures. For children aged 17 and under, the balloon catheter system is intended to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures. The Relieva Ultirra® Nav Sinus Balloon Catheter may be utilized in conjunction with the Acclarent NavWire™ Sinus Navigation Guidewire and CARTO® ENT System to provide access to nasal and sinus spaces, and to confirm placement in the accessed anatomy.

Attribute	**Primary Predicate Device:** Relieva Solo Elite™ Sinus Balloon Catheter	**Secondary Predicate Device:** Medtronic EM Dilation Tool	**Subject Device:** Relieva Ultirra® Nav Sinus Balloon Catheter
Technological Characteristics	Enables dilation of sinus ostia with added capability of irrigating the sinuses.	Allows for dilation of sinus ostia and EM Navigation	Allows for dilation of sinus ostia and EM Navigation
Constructed of Materials Commonly Used in Patient Contacting Medical Devices	Yes	Unknown	Yes
Use a Sinus Guide for Access into Targeted Anatomy	Yes	No	Yes
Guidewire Compatibility with (NavWire or Sinus Illumination System)	Yes 0.035”	No	Yes 0.035”
EtO Sterilized	Yes	Unknown	Yes
Sinuses in which device is intended for use: [Sphenoid, Maxillary, Frontal]	Frontal, Maxillay, Sphenoid	Frontal, Maxillay, Sphenoid	Sphenoid, Maxillary, Frontal
Packaging	Thermoformed tray in pouch	Unknown	Thermoformed tray in pouch
Principles of Operation	Manually operated device. Balloon inflated with sterile saline or water to mechanically dilate sinus ostia.	Unknown	Manually operated device. Balloon inflated with sterile saline or water to mechanically dilate sinus ostia.
Irrigation Capability	Yes	No	No
Sinuses in which device is intended for use: [Sphenoid, Maxillary, Frontal]	Sphenoid, Maxillary, Frontal	Sphenoid, Maxillary, Frontal	Sphenoid, Maxillary, Frontal
EtO Sterilized	Yes	Unknown	Yes

Attribute	**Primary Predicate Device:** Relieva Solo Elite™ Sinus Balloon Catheter	**Secondary Predicate Device:** Medtronic EM Dilation Tool	**Subject Device:** Relieva Ultirra® Nav Sinus Balloon Catheter
Packaging	HDPE backer card in Tyvek/Nylon pouch	Unknown	HDPE backer card in Tyvek/Nylon pouch
Accessory Devices Packed with Device	Stylet	Unknown	Stylet
Principles of Operation	Manually operated device. Balloon inflated with sterile saline or water to mechanically dilate sinus ostia.	Manually operated device. Balloon inflated with sterile saline or water to mechanically dilate sinus ostia.	Manually operated device. Balloon inflated with sterile saline or water to mechanically dilate sinus ostia.
Labeled for compatibility with Image Navigation Systems	No	Yes	Yes

[807.92(b) (1)] Determination of Substantial Equivalence	
Non-Clinical Performance Data:	The Relieva Ultirra® Nav Sinus Balloon Catheter met all performance acceptance criteria including dimensional specifications; balloon burst pressure, joint separation force, deflation time, and balloon cycle fatigue. Shelf life was established per ASTM F1980-07 ASTM F88/F88M-09, ISTA 2A, and ASTM F2096-04 requirements. Testing also showed that the Relieva Ultirra® Nav Sinus Balloon Catheter is biocompatible. The sterilization process has been validated per AAMI/ANSI/ISO 11135:2014 and demonstrated a sterility assurance level of 10^{-6}. The method used for sterilization validation was the overkill (half-cycle approach) in a fixed chamber. Ethylene oxide residuals were tested and met ISO 10993-7:2008 requirements. The subject device is not tested nor labeled as "non-pyrogenic". Packaging shelf life has been established per ASTM F1980-07. Simulated use testing was performed with ENT surgeons performing balloon dilation of the paranasal sinuses utilizing the UltirraNav Sinus Balloon Catheter, Acclarent NavWire Sinus Navigation Guidewire and the CARTO ENT System. The testing demonstrated that the UltirraNav Sinus Balloon used with the Acclarent NavWire and the CARTO ENT System could effectively access the paranasal sinuses. Clinical data was not necessary for the Relieva Ultirra® Nav Sinus Balloon Catheter. The performance data demonstrated that the device performs as intended.
[807.92(b) (2)] Determination of Substantial Equivalence	
Clinical Performance Data	Clinical data was not necessary for the Relieva Ultirra® Nav Sinus Balloon Catheter. The performance data demonstrated that the device performs as intended.
[807.92(b) (3)] Conclusion	
Conclusion from Non-Clinical and Clinical Tests	The Relieva Ultirra® Nav Sinus Balloon Catheter is substantially equivalent to the predicate devices.