May 3, 2019

Acclarent, Inc.
Leena Sorathia
Sr. Regulatory Affairs Specialist
33 Technology Drive
Irvine, California 92618

Re: K190525
Trade/Device Name: RELIEVA ULTIRRA 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: March 1, 2019
Received: March 4, 2019

Dear Leena Sorathia:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Michael Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190525

Device Name

RELIEVA ULTIRRA® Sinus Balloon Catheter

Indications for Use *(Describe)*

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 RELIEVA ULTIRRA® Sinus Balloon Catheter may be utilized in conjunction with TruDi™ NAV Wire and TruDi™ Navigation System to provide access to nasal and sinus spaces, and to confirm placement in the accessed anatomy. It is NOT intended to irrigate from within a target sinus for therapeutic procedures nor to facilitate diagnostic procedures with TruDi™ NAV Wire.

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.

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510(K) SUMMARY

[807.92(a)(1)] Submitter Information

Sponsor/Submitter: Acclarent, Inc.
33 Technology Drive
Irvine, CA 92618

Contact Person: Leena Sorathia
Sr. Regulatory Affairs Specialist
Email: lsorathi@its.jnj.com
Tel: 949-923-4118

Date Summary Prepared: May 3, 2019

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

Device Trade Name:	RELIEVA ULTIRRA® Sinus Balloon Catheter
Classification Name:	Ear, Nose, and Throat Manual Surgical Instrument
Common Name:	Sinus Balloon Catheter
Device Classification:	Class I
Regulation Number:	21 CFR 874.4420
Review Panel:	Ear, Nose, and Throat
Product Code:	LRC

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

Predicate Device: RELIEVA Solo Elite™ Sinus Balloon Catheter (K111254)

Reference Device: RELIEVA UltirraNav® Sinus Balloon Catheter, (K161698)

[807.92(a)(4)] Device Description

Device Description: The RELIEVA ULTIRRA® 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® 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 RELIEVA ULTIRRA® Sinus Balloon Catheter may be utilized in conjunction with TruDi™ NAV Wire and TruDi™ Navigation System to provide access to nasal and sinus spaces, and to confirm placement in the accessed anatomy. It is NOT intended to irrigate from within a target sinus for therapeutic procedures nor to facilitate diagnostic procedures with TruDi™ NAV Wire.

Difference in Indications from Predicate Device

The indications for use statement of the subject device, RELIEVA ULTIRRA® Sinus Balloon Catheter, is similar to predicate device, RELIEVA Solo Elite™ Sinus Balloon Catheter (K111254). The subject and predicate devices are both intended to access and dilate the sinus ostia and paranasal spaces using a balloon.

The proposed revised indications for use for the subject device are largely unchanged from the predicate device with the exception of the additional statement that the device may be used in conjunction with TruDi™ NAV Wire and TruDi™ Navigation System. In addition, the irrigation function of the subject device is not intended to be used in conjunction with the TruDi™ NAV Wire.

The changes in indications for use of the subject device do not raise any significant issues of safety and effectivenessof the device when used as labeled, as demonstrated b performance testing**.**

The difference in indications for use between the subject device and the predicate/reference devices is supported is presented in Table 1 of this summary.

[807.92(a)(6)] Technical Characteristics

Technological Characteristics:	The design and materials of the subject device, RELIEVA ULTIRRA® Sinus Balloon Catheter, are identical to the predicate device RELIEVA Solo Elite™ Sinus Balloon Catheter (K111254). The added capability of the subject device to be used with the TruDi™ NAV Wire and TruDi™ Navigation System did not require any design changes from the predicate device. Like the predicate device, the subject device has the same ballon dilation pressure, material composition, and size specifications. However, the subject device does not allow for the irrigation feature. The subject device is substantially equivalent in technological characteristics, as there are no significant differences in design, fundamental scientific technology, or other features of the device as compared to the predicate device. See Table 1 for a comparison of the technological characteristics between the subject device and the predicate/reference devices.

Attribute	Primary Predicate Device: RELIEVA Solo Elite™ Sinus Guide Catheter (K111254)	Reference Device: RELIEVA ULTIRRA® Nav Sinus Balloon Catheter (K161698)	Subject Device: RELIEVA ULTIRRA® Sinus Balloon Catheter (K190525)
Manufacturer	Acclarent	Acclarent	Acclarent
Common Name	Sinus Balloon Dilation System	Sinus Balloon 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
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 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® Sinus Balloon Catheter* may be utilized in conjunction with the *Acclarent NavWire™ Sinus Navigation Guidewire* and *ACCLARENT® ENT Navigation System* to provide access to nasal and sinus spaces, and to confirm placement in the accessed anatomy.	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 RELIEVA ULTIRRA® Sinus Balloon Catheter may be utilized in conjunction with TruDi™ NAV Wire and TruDi™ Navigation System to provide access to nasal and sinus spaces, and to confirm placement in the accessed anatomy. It is NOT intended to irrigate from within a target sinus for therapeutic procedures nor to facilitate diagnostic procedures with TruDi™ NAV Wire.
Indicated for Children	Yes, for children 17 years and under in maxillary sinus only	Yes, for children 17 years and under in maxillary sinus only	Yes, for children 17 years and under in maxillary sinus only

Attribute	Primary Predicate Device: RELIEVA Solo Elite™ Sinus Guide Catheter (K111254)	Reference Device: RELIEVA ULTIRRA® Nav Sinus Balloon Catheter (K161698)	Subject Device: RELIEVA ULTIRRA® Sinus Balloon Catheter (K190525)
Single Patient Use	Yes	Yes	Yes
Direct Patient Contact	Yes	Yes	Yes
Labeled as Non-Pyrogenic?	No	No	No
Technological Characteristics	Allows for dilation of sinus ostia with the added capability to irrigate.	Allows for dilation of sinus ostia.	Allows for dilation of sinus ostia with the added capability to irrigate when used with the RELIEVA LUMA SENTRY®. It is NOT intended to irrigate from within a target sinus for therapeutic procedures nor to facilitate diagnostic procedures with TruDi™ NAV Wire.
Constructed of Materials Commonly Used in Patient Contacting Medical Devices	Yes	Yes	Yes
Balloon Material	Nylon	Nylon	Nylon
Balloon Diameter and Length	5x16mm, 6x16mm, 7x16mm and 7x24mm	5x16mm	5x16mm, 6x16mm, 7x16mm and 7x24mm
Maximum Inflation Pressure	12 ATM	12 ATM	12 ATM
Flexible Shaft	Yes	Yes	Yes
Deflation Time	< 5 seconds	< 3.6 seconds	< 5 seconds
Catheter Length	250 ± 2 mm	250 ± 2mm	250 ± 2mm
Shaft Design	Dual Lumen	Dual Lumen	Dual Lumen
Used with Guidewire	Yes	Yes	Yes
Guidewire Compatibility	0.035”	0.035”	0.035”

Attribute	Primary Predicate Device: RELIEVA Solo Elite™ Sinus Guide Catheter (K111254)	Reference Device: RELIEVA ULTIRRA® Nav Sinus Balloon Catheter (K161698)	Subject Device: RELIEVA ULTIRRA® Sinus Balloon Catheter (K190525)
Balloon Radiopaque Marker Bands	Yes	Yes	Yes
Balloon Slide Mechanism	Yes	Yes	Yes
Irrigation Capability	Yes	No	Yes, if used with RELIEVA LUMA SENTRY® No, if used TruDi™ NAV Wire
Incorporated Suction	No	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	Yes	Yes
Packaging	HDPE backer card in Tyvek/Nylon pouch	HDPE backer card in Tyvek/Nylon pouch	HDPE backer card in Tyvek/Nylon pouch
Accessory Devices Packed with Device	Stylet	Stylet	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® Sinus Balloon Catheter met all performance acceptance criteria including simulated use testing, 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 F2096-11 requirements. Testing also showed that the RELIEVA ULTIRRA® Sinus Balloon Catheter is biocompatible per ISO 10993-1. 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. Clinical data was not necessary for the RELIEVA ULTIRRA® Sinus Balloon Catheter. The performance data demonstrated that the device performs as intended. The RELIEVA ULTIRRA® Sinus Balloon Catheter passed all intended criteria in accordance with appropriate test criteria and standards.
[807.92(b) (2)] Determination of Substantial Equivalence	
Clinical Performance Data	Clinical data was not necessary for the RELIEVA ULTIRRA® 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	Based on the information provided in this premarket notification, Acclarent concludes that the RELIEVA ULTIRRA® Sinus Balloon Catheter is as safe and effective and substantially equivalent to the predicate device.