DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

February 12, 2016

Acclarent, Inc.
James Patrick Garvey
Senior Manager, Regulatory Affairs
1525-B O'Brien Drive
Menlo Park, California 94025

Re: K153341
Trade/Device Name: Relieva Scout™ Multi-Sinus Dilation System
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose, And Throat Manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: November 18, 2015
Received: November 19, 2015

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 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)*
K153341

Device Name
Relieva Scout™ Multi-Sinus Dilation System

Indications for Use *(Describe)*
For patients aged 18 and older, the Relieva Scout™ Multi-Sinus Dilation System is intended to provide a means to access the sinus space and to dilate the sinus ostia and spaces associated with the sphenoid, frontal, and maxillary sinus cavities for diagnostic and therapeutic procedures. In addition, the device is intended to illuminate within and transilluminate 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)

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)*

APPENDIX A: 510(k) SUMMARY

[807.92(a)(1)] Submitter Information

Sponsor/Submitter:	Acclarent, Inc. 1525-B O'Brien Drive Menlo Park, California 94025
Contact Person:	Patrick Garvey Sr. Manager, Regulatory Affairs Email: pgarvey@its.jnj.com Tel: 650-687-5888
Date Summary Prepared:	February 12, 2016

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

Device Trade Name:	Relieva Scout™ Multi-Sinus Dilation System
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 SCOUT® Sinus Dilation System (K120280) XprESS™ Multi-Sinus Dilation Tool (K121174) RELIEVA® Spin Balloon Sinuplasty System (K111875)

[807.92(a)(4)] Device Description

Device Description:	The Relieva Scout™ Multi-Sinus Dilation System is a sterile, single-use system that is an integrated device with a handle, rail, balloon catheter, and sinus illumination system with an illuminated ball tip. The packaged device contains the sinus balloon catheter an angle selection tool to enable angular bends for multiple sinus access (sphenoid, frontal, maxillary). The device may be used to access the sinus space and the balloon inflated with sterile water or sterile or saline to dilate the sinus ostia and infandibulum. The inflation device is provided separately. The device may be used in Operating Room and physician office settings.

[807.92(a)(5)] Intended Use

Indications for Use:	For patients aged 18 and older, the Relieva Scout™ Multi-Sinus Dilation System is intended to provide a means to access the sinus space and to dilate

	the sinus ostia and spaces associated with the sphenoid, frontal, and maxillary sinus cavities for diagnostic and therapeutic procedures. In addition, the device is intended to illuminate within and transilluminate across nasal and sinus structures.
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.

[807.92(a)(6)] Technical Characteristics

Technological Characteristics:	The Relieva Scout™ Multi-Sinus Dilation System combines features of a rail-based balloon catheter with the tissue expansion effect of balloon dilation. The distal end of the device may be shaped with the angle selection tool to optimize sinus access. Light from an extendable integrated illumination system can be seen via transillumination. See Table 1 for a comparison of the technological characteristics between the Relieva Scout and the predicate devices.

Table 1: Comparison of Technological Characteristics between the Relieva Scout™ Multi-Sinus Dilation System and predicate devices.

Attribute	**Primary Predicate Device:** **RELIEVA SCOUT® Sinus Dilation System (K120280)**	**Secondary Predicate Device:** **XprESS™ Multi-Sinus Dilation Tool (K121174)**	**Predicate Device:** **RELIEVA® Spin Sinus Dilation System (K111875)**	**Subject Device:** **Relieva Scout ™ Multi-Sinus (SMS) Dilation System**
Manufacturer	Acclarent, Inc.	Entellus Medical, Inc.	Acclarent, Inc.	Acclarent, Inc.
Common Name	Sinus Balloon Dilation System	Sinus Balloon Dilation System	Sinus Balloon Dilation System	Sinus Balloon Dilation System
Class	I	I	I	I
Product Code is LRC	LRC	LRC	LRC	LRC
Classification Section	21 CFR 874.4420	21 CFR 874.4420	21 CFR 874.4420	21 CFR 874.4420
Indications for Use	For patients aged 18 and older, the Relieva Scout™ Sinus Dilation System is intended to provide a means to access the frontal sinus space and to dilate the frontal recess, frontal sinus ostia and spaces within the frontal sinus cavity for diagnostic and therapeutic procedures. In addition, the device is intended to illuminate within and transilluminate across nasal and sinus structures.	To access and treat the frontal recesses, sphenoid sinus ostia and maxillary ostia/ethmoid infundibula in adults using a trans-nasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures.	Intended to provide a means to access the sinus space and to dilate the sinus ostia and spaces associated with the paranasal sinus cavities for diagnostic and therapeutic procedures. For children aged 17 and under, the device is intended to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures.	For patients aged 18 and older, the Relieva Scout™ Multi-Sinus Dilation System is intended to provide a means to access the sinus space and to dilate the sinus ostia and spaces associated with the sphenoid, frontal, and maxillary sinus cavities for diagnostic and therapeutic procedures. In addition, the device is intended to illuminate within and transilluminate across nasal and sinus structures. .
Indicated for Children	No	No	Yes	No

Attribute	**Primary Predicate Device:** **RELIEVA SCOUT® Sinus Dilation System (K120280)**	**Secondary Predicate Device:** **XprESS™ Multi-Sinus Dilation Tool (K121174)**	**Predicate Device:** **RELIEVA® Spin Sinus Dilation System (K111875)**	**Subject Device:** **Relieva Scout ™ Multi-Sinus (SMS) Dilation System**
Single Patient Use	Yes	Yes	Yes	Yes
Direct Patient Contact	Yes	Yes	Yes	Yes
Labeled as Non-Pyrogenic?	No	No	No	No
Technological Characteristics	Combines features of a frontal ostium seeker with the tissue expansion effect of balloon dilation. The distal end of the device is permanently curved to optimize frontal ostium access. Light from the distal tip of the integrated sinus illumination system can be seen via transillumination. The device is connected to any standard light source via a light cable and an adapter.	Combines features of a curved suction tip and a frontal ostium seeker (access) with the tissue expansion effect of balloon dilation (treat). The distal end of the device is re-shapeable.	Combines a sinus balloon catheter and a sinus guide catheter to access the sinus space and dilate sinus ostia. A Sinus Illumination System comes packaged with the device and is pre-loaded into the Spin Sinus Dilation System.	Combines a sinus balloon catheter with rail-based balloon guidance to access the sinus space and dilate the sinus ostia. The packaged device contains an angle selection tool to enable angular bends for multiple sinus access. Light from the distal tip of the integrated sinus illumination system can be seen via transillumination.
Constructed of Materials Commonly Used in Patient Contacting Medical Devices	Yes	Yes	Yes	Yes
Balloon Diameter	6mm	5mm to 7mm	6mm	6mm
Balloon Length	24mm	8-20mm	16mm	24mm

Attribute	**Primary Predicate Device:** **RELIEVA SCOUT® Sinus Dilation System (K120280)**	**Secondary Predicate Device:** **XprESS™ Multi-Sinus Dilation Tool (K121174)**	**Predicate Device:** **RELIEVA® Spin Sinus Dilation System (K111875)**	**Subject Device:** **Relieva Scout ™ Multi-Sinus (SMS) Dilation System**
Maximum Inflation Pressure	12 ATM	12 ATM	12 ATM	12 ATM
Single-Handed Use	Yes	Yes	Yes	Yes
Balloon Slide Mechanism	Yes	Yes	Yes	Yes
Rail-Based Design	Yes, preset rail intended for frontal sinus access only	Yes, malleable rail	No	Yes, malleable rail
Handle and Slider System to Facilitate Advancement of a Balloon Catheter on the Distal End	Yes	Yes	Yes	Yes
Uses a Bending Tool to Achieve Target Angles for Access into Targeted Anatomy	No	Yes	No	Yes
Guidewire Capability (Sinus Illumination System)	Yes	Yes	Yes	Yes
Sinuses in which device is intended for use: [Sphenoid, Maxillary, Frontal]	Frontal	Sphenoid, Maxillary, Frontal	Sphenoid, Maxillary, Frontal	Sphenoid, Maxillary, Frontal
EtO Sterilized	Yes	Yes	Yes	Yes

Attribute	**Primary Predicate Device:** **RELIEVA SCOUT® Sinus Dilation System (K120280)**	**Secondary Predicate Device:** **XprESS™ Multi-Sinus Dilation Tool (K121174)**	**Predicate Device:** **RELIEVA® Spin Sinus Dilation System (K111875)**	**Subject Device:** **Relieva Scout ™ Multi-Sinus (SMS) Dilation System**
Packaging	Thermoformed tray in pouch	Backer card in pouch	Backer card in pouch	Thermoformed tray in pouch
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.	Manually operated device. Balloon inflated with sterile saline or water to mechanically dilate sinus ostia.

[807.92(b) (1)] Determination of Substantial Equivalence	
Non-Clinical Performance Data:	Bench testing met all acceptance criteria for attributes such as dimensional attributes, cycle fatigue, balloon burst, and bond separation. Testing in accordance with ISO 10993-1 AAMI ANSI ISO 10993-1:2009/(R) 2013 also showed that the Relieva Scout™ Multi-Sinus Dilation System is biocompatible. The sterilization process was validated per AAMI/ANSI/ISO 11135-1: 2007 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 was established per ASTM F1980-07. 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 Scout™ Multi-Sinus Dilation System. The performance data demonstrated that the device performs as intended.
[807.92(b) (3)] Conclusion	
Conclusion from Non-Clinical and Clinical Tests	The Relieva Scout™ Multi-Sinus Dilation System is substantially equivalent to the predicate devices.