DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 22, 2015

Acclarent, Inc.
Pavan Sethi, Ph.D.
Manager, Regulatory Affairs
1525-B O'Brien Drive
Menlo Park, CA 94025

Re: K143541
Trade/Device Name: Relieva SpinPlus Balloon Sinuplasty System
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose, And Throat Manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: March 20, 2015
Received: March 23, 2015

Dear Dr. Sethi:

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)*
K143541

Device Name
Relieva SpinPlus Balloon Sinuplasty System

Indications for Use *(Describe)*
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 for therapeutic procedures and to facilitate diagnostic procedures.

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)*

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510(K) SUMMARY

Sponsor/Submitter:	Acclarent, Inc. 1525-B O'Brien Drive Menlo Park, California 94025
Contact Person:	Pavan Sethi, Ph.D. Manager, Regulatory Affairs Phone: (650) 687-5413 Fax: (650) 687-4847
Date of Submission:	December 12, 2014
Device Trade Name:	Relieva SpinPlus Balloon Sinuplasty System
Common Name:	Sinus Dilation System
Device Classification:	Class I
Regulation Number:	21 CFR 874.4420
Classification Name:	Ear, Nose, and Throat Manual Surgical Instrument
Product Code:	LRC
Predicate Devices:	Relieva Spin Sinus Dilation System (Primary Predicate, K111875) Relieva Solo Elite Sinus Balloon Catheter (K111254) Relieva Luma Sinus Illumination System (K071845)
Device Description:	The Relieva SpinPlus Balloon Sinuplasty System is an integrated device that incorporates an ergonomically designed Handle, an illuminated Guidewire, a Sinus Balloon Catheter, and a Guide Catheter. The Sinus Balloon Catheter enables sinus irrigation without instrument exchanges. The principles of operation of SpinPlus are similar to the predicate devices in allowing for access and enlargement of sinus ostia, and irrigation from within the target sinus.
Indications for Use:	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 for therapeutic procedures and to facilitate diagnostic procedures.
Technological Characteristics:	The Relieva SpinPlus Balloon Sinuplasty System combines a Sinus Guide Catheter and Handle Assembly (integrated with Sinus Balloon Catheter, Sinus Irrigation and Illuminated Sinus Guidewire) into a single device.
Performance Data:	Bench testing met all acceptance criteria for attributes such as simulated use testing, dimensional attributes, cycle fatigue, balloon burst, bond separation, irrigation flow rate and wire light output. Testing also showed that the SpinPlus Balloon Sinuplasty System is biocompatible. 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". Packaging shelf life has been established to be 3 months per ASTM F1980-07. Clinical data were not necessary for the SpinPlus Balloon Sinuplasty System. The performance data demonstrate that the device performs as intended.