K111875

OCT 11 2011

Acclarent

510(K) SUMMARY

Sponsor/Submitter:	Acclarent, Inc. 1525-B O'Brien Drive Menlo Park, California 94025
Contact Person:	Keri Yen Manager, Regulatory and Clinical Phone: (650) 687-5874 Fax: (650) 687-4449
Date of Submission:	August 30, 2011
Device Trade Name:	Relieva Spin Sinus Dilation 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 Acella Sinus Balloon Catheter (K073041) Entellus Medical XprESS Multi-Sinus Dilation Tool (K102003)
Device Description:	The Relieva Spins Sinus Dilation System is comprised of three components: Handle System, Sinus Guide Catheter Tip, and Sinus Balloon Catheter. The Handle System unites the various components into one device. A suction line is embedded in the Handle System which can be actuated by the user covering the suction port. The Sinus Guide Catheter Tip is a sinus guide catheter that is available in three shapes and attaches to the Handle System on the distal end. The Sinus Balloon Catheter is a flexible catheter with a balloon on the distal tip; one lumen is used for inflation of the sinus balloon and the second permits passage of a sinus guidewire. A hypotube is incorporated on the proximal end of the device to provide rigidity as the Sinus Balloon Catheter is advanced and retracted in the Handle System. There are several markers placed along the Sinus Balloon Catheter to aid in positioning under direct endoscopic visualization. A sinus guidewire is packaged with the Relieva Spin Sinus Dilation System.

Indications for Use: The Relieva Spin 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 paranasal sinus cavities for diagnostic and therapeutic procedures. For children aged 17 and under, the Relieva Spin Sinus Dilation System is intended to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures.

Technological Characteristics: The technological characteristics of the subject device are similar to its predicate devices.

Attribute	**Predicate Device (Relieva Acella Sinus Balloon Catheter)**	**Predicate Device (XprESS Multi-Sinus Dilation Tool)**	**Subject Device (Relieva Spin Sinus Dilation System)**
510(k) number	K073041	K102003	TBD
Manufacturer	Acclarent	Entellus Medical	Same, Acclarent
Balloon Diameters	6mm	6mm	Same, 6mm
Balloon Length	12mm	18mm	16mm
Maximum Inflation Pressure	14 ATM	12 ATM	Same, 12 ATM
Suction Incorporated	No	Yes	Same, Yes
Balloon Slide Mechanism	No	Yes	Same, Yes
Technological Characteristics	Combines a sinus balloon catheter and a sinus guidewire to access and dilate sinuses.	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 and dilate sinuses.
Packaged Devices	None	Packaged with inflation device and infusion line	Packaged with Relieva Luma Sentry Sinus Illumination System

Performance Data: Bench testing met all acceptance criteria for attributes such as dimensional, cycle fatigue, balloon burst, and joint separation. Testing also showed that Spin is biocompatible.

The sterilization process is 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 were tested and meet ISO 10993-7:2008 requirements. The subject device is not tested or labeled as "non-pyrogenic".

Packaging shelf life was established per ASTM F1980-07, ASTM

	F88/F88M-09, ISTA 2A-11, and ASTM F2096-04 requirements. Clinical data was not necessary for Spin. The performance data demonstrates that the subject device performs as intended.
Summary of Substantial Equivalence:	The Relieva Spin Sinus Dilation System is substantially equivalent to the predicate device as confirmed through relevant tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 1 1 2011

Acclarent, Inc.
c/o Ms. Keri Yen
Manager, Regulatory and Clinical
1525-B O'Brien Drive
Menlo Park, CA 94025

Re: K111875
Trade/Device Name: Relieva Spin 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: August 30, 2011
Received: August 31, 2011

Dear Ms. Yen:

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.

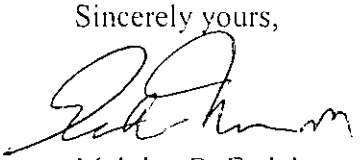
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111875

Acclarent

APPENDIX B: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K111875

Trade Name: Relieva Spin Sinus Dilation System

Common Name: Sinus Dilation System

Indications For Use: The Relieva Spin 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 paranasal sinus cavities for diagnostic and therapeutic procedures. For children aged 17 and under, the Relieva Spin Sinus Dilation System is intended to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K111875

(Posted November 13, 2003)