K120280

NOV 5 2012

510(k) SUMMARY

Sponsor/Submitter:	Acclarent, Inc. 1525-B O'Brien Drive Menlo Park, California 94025
Contact Person:	Daniel Harfe Director, Clinical and Regulatory Affairs Phone: (650) 687-6056 Fax: (650) 687-4847
Date of Submission:	January 27, 2012
Device Trade Name:	Relieva Seeker 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 (K111875) Entellus Medical XprESS Multi-Sinus Dilation Tool (K102003) Relieva Luma Sinus Illumination System (K071845)
Device Description:	The Relieva Seeker Balloon Sinuplasty System (Seeker) is an integrated device with a low-profile rail, balloon catheter, sinus illumination system with an illuminated ball tip, and a handle. The sinus balloon may be inflated to dilate the frontal recess, frontal sinus ostia, and spaces within the frontal sinus cavity.

Indications for Use:	For patients aged 18 and older, the Relieva Seeker Balloon Sinuplasty 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.
Technological Characteristics:	The Seeker Balloon Sinuplasty System 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 an extendable integrated illumination system can be seen via transillumination.
Performance Data:	Bench testing met all acceptance criteria for attributes such as dimensional attributes, cycle fatigue, balloon burst, and bond separation. Testing also showed that the Seeker Balloon Sinuplasty System is biocompatible. Sterilization of the subject device is achieved by ethylene oxide, which was validated according to 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, ISTA 2A:2011, ASTM F88-09, ASTM F2096-11, F1886, and F1929-98 requirements. Clinical data were not necessary for the Seeker Balloon Sinuplasty System. The performance data demonstrate that the device performs as intended.
Summary of Substantial Equivalence:	The Relieva Seeker Sinus Dilation System is substantially equivalent to the predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

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Acclarent, Inc.
% Mr. Daniel Harfe
Director, Regulatory & Clinical, Rhinology
1525-B O'Brien Drive
Menlo Park, CA 94025

Re: K120280
Trade/Device Name: Relieva Seeker 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: October 19, 2012
Received: October 22, 2012

Dear Mr. Harfe:

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,

Kesia Alexander

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

APPENDIX B: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K120280

Trade Name: Relieva Seeker Balloon Sinuplasty™ System

Common Name: Sinus Dilation System

Indications For Use: For patients aged 18 and older, the Relieva Seeker Balloon Sinuplasty 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.

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)

(Posted November 13, 2003)

Daniel C Clapp

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

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