K110687

OCT - 7 2011

8. 510(K) SUMMARY

Sponsor/Submitter:	Acclarent, Inc. 1525-B O'Brien Drive Menlo Park, California 94025
Contact Person:	Dean Knight Senior Manager, Regulatory Affairs Phone: (650) 687-4807 Fax: (650) 687-4449
Date of Submission:	March 9, 2011
Device Trade Name:	Relieva Stratus Pro MicroFlow Spacer (Frontal)
Common Name:	Sinus cannula
Device Classification:	Class I
Regulation Number:	21 CFR 878.4800
Classification Name:	Manual surgical instrument for general use
Product Code:	KAM
Predicate Device:	Relieva Stratus MicroFlow Spacer (K093594)
Device Description:	The Relieva Stratus Pro MicroFlow Spacer (Frontal) is a device that maintains an opening at the target sinus for up to 14 days postoperatively. The device can be manually removed during an office follow-up visit.
Indications for Use:	The MicroFlow Spacer is indicated for use as a postoperative spacer to maintain an opening to the frontal sinuses within the first 14 days following surgery. The MicroFlow Spacer also helps to prevent obstruction.
Technological Characteristics:	The Relieva Stratus Pro MicroFlow Spacer (Frontal) is designed to be implanted into the frontal sinuses and to maintain its position by a self-retention mechanism. The safety and effectiveness of injecting solutions other than saline solution in the catheter have not been established.
Performance Data:	The Relieva Stratus Pro MicroFlow Spacer (Frontal) met all performance acceptance criteria. The sterilization process is validated per AAMI/ANSI/ISO 11135-1: 2007. The device meets the requirements for a sterility assurance level of 10^{-6}. The device is non-pyrogenic per ANSI/AAMI ST72:2002

	requirements. Post-sterilization ethylene oxide residuals were tested and meet ISO 10993-7:2008 requirements. Shelf life was established at 13 months per ASTM F1980-07 requirements. Package integrity at the end of the shelf life was established per ASTM F88-07A, ISTA 2A-08, and ASTM F2096-04 requirements.
Summary of Substantial Equivalence:	The Relieva Stratus Pro MicroFlow Spacer (Frontal) is substantially equivalent to the predicate device as confirmed through relevant performance 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

Acclarent, Inc.
c/o Mr. Dean Knight
Senior Manager, Regulatory Affairs
1525-B O'Brien Drive
Menlo Park, CA 94025

OCT - 7 2011

Re: K110687
Trade/Device Name: Relieva Stratus Pro MicroFlow Spacer (Frontal)
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: Class I
Product Code: KAM
Dated: September 7, 2011
Received: September 9, 2011

Dear Mr. Knight:

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

7. STATEMENT OF INDICATIONS FOR USE

Indications for Use

510(k) Number (if known): K110687

Device Name: Relieva Stratus Pro MicroFlow Spacer (Frontal)

Indications for Use:

The MicroFlow Spacer (Frontal) is indicated for use as a postoperative spacer to maintain an opening to the frontal sinuses within the first 14 days following surgery. The MicroFlow Spacer also helps to prevent obstruction.

Prescription Use ✓ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel C Clapp

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

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