K071845

Acclarent

SEP 28 2007

APPENDIX A: 510(k) SUMMARY

Sponsor/Submitter:	Acclarent, Inc. 1525-B O'Brien Drive Menlo Park, California 94025
Contact Person:	Keri Yen Regulatory Affairs Specialist Phone: (650) 687-5874 Fax: (650) 687-4449
Date of Submission:	July 3, 2007
Device Trade Name:	*Relieva Luma*™ Sinus Illumination System
Common Name:	Sinus Guidewire
Device Classification:	Class I
Regulation Number:	21 CFR 878.4800
Classification Name:	Manual surgical instrument for general use
Product Code:	KAM
Predicate Device:	*Relieva*™ Sinus Guidewire (K043445)
Device Description:	The *Relieva Luma*™ Sinus Illumination System is a flexible device that transmits light at the distal tip. The system also contains two accessories: a light cable and an adapter.
Indications for Use:	The *Relieva Luma*™ Sinus Illumination System is intended to provide means to access the sinus space for diagnostic and therapeutic procedures in conjunction with other nasal and sinus products. It is also intended to illuminate within and transilluminate across nasal and sinus structures.
Technological Characteristics	The *Relieva Luma*™ Sinus Illumination System is a device that allows for access to the desired sinus space. Light from the distal tip of the device can be seen via transillumination. The device is connected to any standard light source via a light cable and an adapter.
Performance Data	The *Relieva Luma*™ Sinus Illumination System met all performance testing acceptance criteria.
Summary of Substantial Equivalence:	The *Relieva Luma*™ Sinus Illumination System 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
9200 Corporate Boulevard
Rockville MD 20850

Acclarent, Inc.
c/o Keri Yen
Regulatory Affairs Specialist
1525-B O'Brien Drive
Menlo Park, CA 90425

SEP 28 2007

Re: K071845
Trade/Device Name: Relieva Luma™ Sinus Illumination System
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: Class I
Product Code: KAM
Dated: August 30, 2007
Received: August 31, 2007

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. B. Eydelman, MD

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

K071845

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APPENDIX B: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K071845

Trade Name: *Relieva Luma*™ Sinus Illumination System

Common Name: Sinus Guidewire

Indications For Use: The *Relieva Luma*™ Sinus Illumination System is intended to provide a means to access the sinus space for diagnostic and therapeutic procedures in conjunction with other nasal and sinus products. It is also 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)

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

510(k) Number K071845