K073041

Acclarent

APPENDIX A: 510(k) SUMMARY

MAR 11 2008

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:
October 26, 2007

Device Trade Name:
Relieva™ Sinus Balloon Catheter
Relieva Acella™ Sinus Balloon Catheter

Common Name:
Sinus Balloon Catheter
Sinus Balloon Catheter—Integrated Wire

Device Classification:
Class I

Regulation Number:
21 CFR 874.4420

Classification Name:
ENT Manual Surgical Instrument

Product Code:
LRC

Predicate Devices:
Relieva Sinus Balloon Catheter (K043527)
Relieva Acella Sinus Balloon Catheter (K061903)

Device Description:
The Relieva Sinus Balloon Catheter is a catheter designed to dilate the sinus ostia and paranasal spaces in adults and maxillary sinus spaces in children.

The Relieva Acella Sinus Balloon Catheter is a catheter designed to access and to dilate the sinus ostia and paranasal spaces in adults and maxillary sinus spaces in children.

Indications for Use:
Relieva Sinus Balloon Catheter is an instrument intended to dilate sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures. For children aged 17 and under, the balloon catheter system is intended to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures.

Relieva Acella Sinus Balloon Catheter is an instrument intended to dilate sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures. For children aged 17 and under, the balloon catheter system is intended to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures.

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Technological Characteristics:	The Relieva Sinus Balloon Catheter and the Relieva Acella Sinus Balloon Catheter utilize a balloon to dilate blocked nasal passageways. The balloon is inflated with a high pressure inflation device.
Performance Data:	The Relieva Sinus Balloon Catheter met all performance acceptance criteria. The Relieva Acella Sinus Balloon Catheter met all performance criteria.
Summary of Substantial Equivalence:	The clarifying statement added to the indications for use does not impact the intended use, performance, fundamental scientific technology, or safety and effectiveness of the subject device and therefore the subject device is substantially equivalent to the predicate devices. The Relieva Sinus Balloon Catheter and the Relieva Acella Sinus Balloon Catheter are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2008

Acclarent, Inc
c/o Keri Yen
1525-B O'Brien Drive
Menlo Park, CA 94025

Re: K073041
Trade/Device Name: Relieva™ Sinus Balloon Catheter
Relieve™ Acella Sinus Balloon Catheter
Regulation Number: 21 CFR 874.4800
Regulation Name: ENT Manual Surgical Instrument
Regulatory Class: Class I
Product Code: KAM
Dated: February 18, 2008
Received: February 19, 2008

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,

Malvina B. Eydelman, M.D.

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

K073041

Acclarent

Traditional 510(k)

Relieva™ Sinus Balloon Catheter
Relieva Acella™ Sinus Balloon Catheter

APPENDIX B: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K073041

Trade Name: *Relieva*™ Sinus Balloon Catheter
Relieva™ Acella Sinus Balloon Catheter

Common Name: Sinus Balloon Catheter
Sinus Balloon Catheter—Integrated Wire

Indications For Use: Relieva Sinus Balloon Catheter is an instrument intended to dilate sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures. For children aged 17 and under, the balloon catheter system is intended to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures.

Relieva Acella Sinus Balloon Catheter is an instrument intended to dilate sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures. For children aged 17 and under, the balloon catheter 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)

(Posted November 13, 2003)

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

510(k) Number K073041