K090660

Acclarent

APPENDIX A: 510(k) SUMMARY

JUN 12 2009

Sponsor/Submitter:
Acclarent, Inc.
1525-B O'Brien Drive
Menlo Park, California 94025

Contact Person:
Keri Yen
Sr. Regulatory Affairs Specialist
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Date of Submission:
March 11, 2009

Device Trade Name:
TBD

Common Name:
Airway Balloon Catheter and Accessories

Device Classification:
Airway Balloon Catheter (Class II)
Relieva Inflation Device (Class I)

Regulation Number:
Airway Balloon Catheter (21 CFR 874.4680)
Relieva Inflation Device (21 CFR 874.4420)

Classification Name:
Bronchoscope (flexible or rigid) and accessories
Ear, nose, and throat manual surgical instrument

Product Code:
KTI
LRC

Predicate Devices:
Boston Scientific CRE Pulmonary Balloon Dilation Catheter (K023337)
Acclarent Relieva Sinus Balloon Catheter (K073041)
Acclarent Relieva Sinus Inflation Device (K052198)
Boston Scientific Alliance II Inflation System (K Number Unknown)

Device Description:
The Airway Balloon Catheter is a catheter with a high pressure balloon on the distal tip. The device is designed with a coaxial lumen for inflation and guidewire access, if required. There are two accessories for the Airway Balloon Catheter: Inflation Device and Relieva Vigor Guidewire (optional).

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Indications for Use:	The Airway Balloon Catheter is an instrument intended to dilate strictures of the airway tree. The Inflation Device is an instrument intended to inflate, deflate and monitor pressure in balloon catheters used in sinus procedures and dilation of the airway tree.
Technological Characteristics:	The Airway Balloon Catheter and Accessories enlarge strictures in the airway tree. The technological characteristics of the subject device are similar to its predicate devices.
Performance Data:	The Airway Balloon Catheter and Accessories met all performance acceptance criteria.
Summary of Substantial Equivalence:	The Airway Balloon Catheter is substantially equivalent to the predicate device as confirmed through relevant tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Acclarent, Inc.
c/o Debra Cogan
Sr. Regulatory Affairs Manager
1525-B O'Brien Drive
Menlo Park, CA 94025

JUN 12 2009

Re: K090660
Trade/Device Name: Airway Balloon Catheter Inflation Device
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and Accessories
Regulatory Class: II
Product Code: KTI
Dated: May 21, 2009
Received: May 22, 2009

Dear Ms. Cogan:

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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

Acclarent K090660

APPENDIX B: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K090660

Trade Name: TBD

Common Name: Airway Balloon Catheter
Inflation Device

Indications For Use: The Airway Balloon Catheter is an instrument intended to dilate strictures of the airway tree.

The Inflation Device is an instrument intended to inflate, deflate and monitor pressure in balloon catheters used in sinus procedures and dilation of the airway tree.

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)

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

510(k) Number K090660

(Posted November 13, 2003)