K110218

MAR 3 1 2011

Acclarent

APPENDIX A: 510(k) SUMMARY

Sponsor/Submitter:	Acclarent, Inc. 1525-B O'Brien Drive Menlo Park, California 94025
Contact Person:	Keri Yen Regulatory Affairs Manager Phone: (650) 687-5874 Fax: (650) 687-4449
Date of Submission:	January 24, 2011
Device Trade Name:	Inspira AIR Balloon Dilation System
Common Name:	Airway Balloon Catheter
Device Classification:	Class II
Regulation Number:	21 CFR 874.4680
Classification Name:	Bronchoscope (flexible or rigid) and accessories
Product Code:	KTI
Predicate Devices:	Acclarent Airway Balloon Catheter and Accessories (K090660) Boston Scientific CRE Pulmonary Balloon Dilation Catheter (K023337)
Device Description:	The Modified 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 stylet access, if required. The Modified Airway Balloon Catheter encompasses a 18x40mm balloon catheter and reduces the deflation time specification.
Indications for Use:	The Modified Airway Balloon Catheter is an instrument intended to dilate strictures of the airway tree.

Technological Characteristics: The technological characteristics of the subject device are similar to its predicate devices.

Attribute	Airway Balloon Catheter (K090660)	CRE Pulmonary Balloon Dilation Catheter (K023337)	Modified Airway Balloon Catheter
Balloon Diameters	5 mm 7 mm 10 mm 14 mm	8-9-10 mm 10-11-12 mm 12-13.5-15 mm 15-16.5-18 mm 18-19-20 mm	18mm
Balloon Length	24 mm 40 mm	30 mm 55 mm	40 mm
Deflation Time	≤15 seconds ≤25 seconds	Unknown	≤15 seconds
Maximum Inflation Pressure	10-16 ATM	6-9 ATM	8 ATM
Flexible	Yes	Yes	Yes
Shaft Design	Coaxial Lumen	Coaxial Lumen	Coaxial Lumen
Used with Stylet	Optional	Yes (Guidewire)	Optional
Technological Characteristics	To dilate strictures of airway tree	To dilate strictures of airway tree	To dilate strictures of airway tree

Performance Data: The Modified Airway Balloon Catheter and Accessories met all performance acceptance criteria.

Summary of Substantial Equivalence: The Modified 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Acclarent, Inc.
c/o Ms. Keri Yen
Manager, Regulatory and Clinical
1525-B O'Brien Dr.
Menlo Park, CA 94025

MAR 31 2011

Re: K110218
Trade/Device Name: Inspira AIR Balloon Dilation System
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Dated: March 2, 2011
Received: March 3, 2011

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. 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

K110218

Acclarent

APPENDIX B: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K110218

Trade Name: Inspira AIR Balloon Dilation System

Common Name: Airway Balloon Catheter

Indications For Use: The Airway Balloon Catheter is an instrument intended to dilate strictures 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)

(Posted November 13, 2003)

Daniel C Clapp

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

510(k) Number K110218