APPENDIX A: 510(k) SUMMARY

AUG 18 2006

Sponsor/Submitter:	Acclarent, Inc. 1525-B O'Brien Drive Menlo Park, California 94025
Contact Person:	Keri Yen Quality Engineer Phone: (650) 687-5874 Fax: (650) 687-5889
Date of Submission:	June 30, 2006
Device Trade Name:	To be determined
Common Name:	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 Device:	Relieva Sinus Balloon Catheter (K043527) Relieva Sinus Guidewire (K043445)
Device Description:	The Sinus Balloon Catheter—Integrated Wire is a sinus balloon catheter that has an integrated guidewire. The Sinus Balloon Catheter—Integrated Wire allows access to and dilation of the sinus ostia and paranasal spaces with a single device.
Indications for Use:	To provide a means to access the sinus space and to dilate the sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures.
Technological Characteristics	The Sinus Balloon Catheter—Integrated Wire is a device that allows for the capability to access and to dilate the sinus ostia with the same device.
Performance Data	The Sinus Balloon Catheter—Integrated Wire met all performance testing acceptance criteria.
Summary of Substantial Equivalence:	The Sinus Balloon Catheter—Integrated Wire is substantially equivalent to the predicate devices as confirmed through relevant performance tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 2006

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

Re: K061903
Trade/Device Name: Sinus Balloon Catheter – Integrated Wire
Regulation Number: 21 CFR 874.4420
Regulation Name: ENT Manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: July 31, 2006
Received: August 1, 2006

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

APPENDIX B: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K061903

Trade Name: To be determined

Common Name: Sinus Balloon Catheter--Integrated Wire

Indications For Use: To provide a means to access the sinus space and to dilate the sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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(Posted November 13, 2003)

Prescription Use ✓
(Per 21 CFR 801.109)