APPENDIX A: 510(k) SUMMARY

Sponsor/Submitter:	Acclarent, Inc. 1525-B O'Brien Drive Menlo Park, California 94025
Contact Person:	Debbie Cogan Quality Engineer Phone: (650) 687-5857 Fax: (650) 687-5889
Date of Submission:	October 6, 2006
Device Trade Name:	To be determined
Common Name:	MicroEndoscope
Device Classification:	Class II
Regulation Number:	21 CFR 874.4760
Classification Name:	Nasopharyngoscope (flexible or rigid) and accessories
Product Code:	EOB
Predicate Device:	Pollux Endoscopy Sinuscope (K002214) Acueity ViaDuct MicroEndoscope and Accessories (K011189) EBI VueCath Spinal Endoscopic System (K010179)
Device Description:	The MicroEndoscope is a semi-rigid fiberscope that allows for visualization of the ear, nose, and throat. The device is labeled non-sterile and must be sterilized prior to use. The MicroEndoscope is accompanied by a camera coupler, which allows the MicroEndoscope to connect to a standard endoscopic camera.
Indications for Use:	The MicroEndoscope is intended to provide an endoscopic means to view a body cavity for ear, nose or throat procedures.
Technological Characteristics	The MicroEndoscope contains illumination and image fibers that transmit an image from the distal to the proximal end of the device.
Performance Data	The MicroEndoscope met all performance testing acceptance criteria.
Summary of Substantial Equivalence:	The MicroEndoscope is substantially equivalent to the predicate devices as confirmed through relevant performance tests.

OCT 24 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Acclarent, Inc.
c/o Debbie Cogan
Clinical and Regulatory Manager
1525-B O'Brien Drive
Menlo Park, CA 94025

OCT 2 4 2006

Re: K063078
Trade/Device Name: MicroEndoscope
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOB
Dated: October 6, 2006
Received: October 10, 2006

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 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,

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): K063078

Trade Name: To be determined

Common Name: MicroEndoscope

Indications For Use: The MicroEndoscope is intended to provide an endoscopic means to view a body cavity for ear, nose or throat 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)

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(Posted November 13, 2003)

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

510(k) Number K063078

Prescription Use X
(Per 21 CFR 801.109)