K110097

Acclarent

MAY 2 7 2011

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 Preparation:	May 20, 2011
Device Trade Name/ Model Number:	Acclarent Cyclops Multi-Angle Endoscope CYE002
Common Name:	Endoscope
Device Classification:	Class II
Regulation Number:	21 CFR 874.4760
Classification Name:	Nasopharyngoscope (Flexible or Rigid)
Product Code:	EOB
Predicate Devices:	Acclarent Cyclops Multi-Angle Endoscope (K100577)
Device Description:	The Acclarent Cyclops Multi-Angle Endoscope is a 4mm rigid unchanneled endoscope that has the capability of varying direction of view from 10° to 90°, which is altered by the direction of view dial. The direction of view is indicated by visible markings on the scope body. Cyclops provides a 55° field of view and a depth of focus from 5 mm to 40mm. The device shaft can also rotate 320° to allow for visualization of structures without rotating the device; this is controlled by the shaft rotation dial. Small rare-earth permanent magnets are incorporated into the proximal scope control body (≤10 gauss at 2cm) and drive the change in the direction of view. A standard eyepiece located on the proximal end of the device is compatible with a standard camera coupler. The light post on the subject device is compatible with an ACMI light source. There are two stainless steel adapters that accompany the Acclarent Cyclops Multi-Angle Endoscope to facilitate connection with Wolf or Storz/Olympus medical light sources.

The adapters connect to the light post. The Acclarent Cyclops Multi-Angle Endoscope is a reusable device and must be cleaned and sterilized according to the user manual prior to every use.

Indications for Use: The Acclarent Cyclops Multi-Angle Endoscope is intended to provide an endoscopic means to view the nasal cavity and nasopharynx in an operating room environment.

Technological Characteristics:

Attribute	Predicate Device (Acclarent Cyclops Multi-Angle Endoscope)	Subject Device (Acclarent Cyclops Multi-Angle Endoscope)
510(k) number	K100577	K110097
Model Number	CYE001	CYE002
Rigidity	Rigid	Same
Viewing Optics	Lens (Sapphire cover)	Same
Depth of View	5-45 mm	Same
Field of View	60°	55°
Direction of View	10° to 100°	10° to 90°
Shaft Body Diameter	4mm	Same
Working Length	6.89 inches (175mm)	Same
Magnetic Strength	≤10 gauss at 2cm	Same
Illumination Fibers	Glass Fibers	Same

Performance Data: Performance testing of the Acclarent Cyclops Multi-Angle Endoscope consisted of bench testing and a cadaver study. Bench testing met all acceptance criteria for attributes such as distal shaft diameter, working length, field of view, fixed focus, direction of view, rotation of view, illumination, scope resolution, dial actuation forces, temperature testing, field strength testing of magnets, electrical safety, EMC testing, durability testing, environmental conditioning, compression testing, random vibration testing, and shock (free fall drop) testing. Temperature testing consisted of attaching thermocouples at nine locations using adhesive and measuring the temperature at steady state. Test samples were connected to a 300W Xenon light source at 100% light output with both 3.5mm and 5.0mm light cables. The time to heat and time to cool was also evaluated. Clinical data was not necessary for the subject device. The performance data demonstrates that the Acclarent Cyclops Multi-Angle Endoscope performs as

	intended according to IEC 60601-2-18, IEC 60601-1-2, ISO10993-1, ISO 8600-3, ISO 8600-5.
Validated Reprocessing Methods:	• Full manual cleaning with extended enzymatic soak plus general instrument automated washer • Pre-vacuum steam sterilization (wrapped) In validating the above, the following standards were referenced: AAMI/ANSI ST35, AAMI TIR 12, AAMI TIR 30, and ANSI/AAMI ST79 A1/A2, ANSI/AAMI ST8, ANSI/AAMI ST81, ASTM E1766.
Summary of Substantial Equivalence:	The Acclarent Cyclops Multi-Angle Endoscope is substantially equivalent to the predicate devices as confirmed through relevant performance tests and attributes.

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

MAY 27 2011

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

Re: K110097
Trade/Device Name: Acclarent Cyclops Multi-Angle Endoscope (Model CYE002)
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible or Rigid)
Regulatory Class: Class II
Product Code: EOB
Dated: April 26, 2011
Received: April 27, 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.

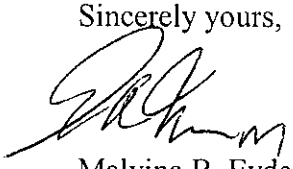
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

Indications for Use

510(k) Number (if known): K110097

Device Name: Acclarent Cyclops Multi-Angle Endoscope (Model CYE002)

Indications For Use: The Acclarent Cyclops Multi-Angle Endoscope is intended to provide an endoscopic means to view the nasal cavity and nasopharynx in an operating room setting.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Rudy CRNP

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

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