K060869

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MAY 11 2006

200 Expressway Court
Virginia Beach, Virginia 23462, USA

510(k) Summary

The information contained in this premarket notification 510(k) summary is submitted as required by 21 CFR 807.92(c):

Submitter:	Right Medical Products LLC. 200 Expressway Court, Virginia Beach, VA. USA 23462
Contact Person:	Harumi Kumahara Regulatory Affairs Coordinator Phone: 416-398-3306 X244 Fax: 416-631-8272 hkumahara@rightmedical.com
Date Prepared:	February 2006
Trade Name:	RS-1000 Zoom Slitlamp with option
Common Name:	AC-Powered Slitlamp Biomicroscope
Product Code:	HJO
Class:	Class II
Classification panel:	86/ Ophthalmic
Predicate Device:	Substantial Equivalence is claimed based on the Marco Ophthalmic branded Ultra G5 zoom slitlamp (K930438),
Device Description:	The RS-1000 Zoom slitlamp microscope consists of a microscope with a halogen lamp which illuminates the inner eye for examination with an

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optional attachment for photographic or video capabilities and an illumination power supply.

Intended Uses:	The RS-1000 Zoom slitlamp is a diagnostic illumination microscope intended to examine the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affects the structural properties of the anterior eye segment.
Technological Characteristics:	The technological characteristics with option are the same or similar to those found with the predicate devices where the eye is examined by projecting light onto it.
Performance testing:	The RS-1000 Zoom slitlamp was tested in accordance to IEC 60601-1 and IEC 60601-1-2 was found to meet all safety and electromagnetic compatibility requirements of the standards.
Conclusion:	Based on non-clinical testing results, the RS-1000 Zoom slitlamp with option has demonstrated that it is equivalent to the predicate devices with respect to intended uses, technological characteristics and safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2006

Right Medical Products, LLC.
c/o Harumi Kumahara
200 Expressway Court
Virginia Beach, VA 23462

Re: K060869
Trade/Device Name: RS-1000 Zoom Slitlamp with option
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slitlamp biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: March 20, 2006
Received: March 30, 2006

Dear Ms. Kumahara:

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 (301) 827-8910. 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 (301) 443-6597 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

Indications for Use

510(k) Number (if known): _____

Device Name: RS-1000 Zoom Slitlamp with option

Indications for Use:

The RS-1000 Zoom Slitlamp with option is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.

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)

Dennis L. McCarthy

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

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