K110129

AUG 3 0 2011

510(k) Summary

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

Submitter:	RIGHTMEDICAL Products LLC. 5325 Cleveland Street, Virginia Beach, VA. USA 23462
Contact Person:	Mélanie Deslauriers Regulatory Affairs Coordinator Phone: 416-615-0185 Fax: 416-631-8272 regaffairs@rightmedical.com
Date Prepared:	August 2011
Trade Name:	Righton Zoom Slit Lamp NS-2D with option
Common Name:	AC-Powered Slit lamp Biomicroscope
Product Code:	HJO
Class:	Class II
Regulation:	21 CFR 886.1850
Predicate Device:	Substantial Equivalence of the Slit Lamp is claimed based on the Appasamy A1A-11 Zoom Slit Lamp (K082031). Substantial Equivalence of the data collection and image manipulation software is claimed based on the EyeCap Imaging System (K000368) and on the Nidek Navis Software (K013694).
Device Description:	The NS-2D zoom slit lamps are designed for ophthalmic observation and microphotography. These slit lamps feature zoom stereoscopic converging microscopes that can be used for ophthalmic observation. Each instrument consists primarily of the main unit and the illumination power supply unit.

Substantial Equivalence Tables:

	Righton NS-2D Zoom	Appasamy A1A 11 Zoom (K082031)
Intended Use	Used in 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.	Used in 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.
Method of operation	Converging-type Zoom Microscope (12.5°) (Greenough Type)	Converging-type Zoom Microscope (Galilean Type)
Exposure parameters	Magnification Change: Continuous by manual zoom Eyepiece: 12.5x and 15.0x PD Range: 52mm to 75mm Slit Width: 0mm to 16mm continuously variable Slit Apertures: ø0.2, 1, 2, 5, 10, 14, 16 mm, 0 to 12 mm continuously variable Slit Inclination: 0°, 5°, 10°, 15° and 20° Slit Rotation: 90° to right and left Diopter adjustment: -8D to +8D for the 12.5x eyepiece and -6D to +6D for the 15x eyepiece Working Distance: 100mm	Magnification Change: Continuous by manual zoom Eyepiece: 12.5x PD Range: 55mm to 75mm Slit Width: 0mm to 14mm Slit Apertures: 0mm to 14mm, ø0.2, 1, 3, 4, 6, 10, 14mm Slit Inclination: 0°, 5°, 10°, 15° and 20° Slit Angles: 0° to 180° Diopter adjustment: -6D to +6D Working Distance: 100mm
Total Magnification	5.9x to 32.5x for 12.5x eyepiece 7.1x to 39x for 15.0x eyepiece	5.5x to 35.0x
Filters	Transparent Heat Absorption ND (28%) Green Cobalt Blue	Transparent Heat Absorption Green Cobalt Blue
Fixation Light	LED (Class 1)	LED
Data collection and/or display system	Yes	NAV
Flammability of materials	This instrument is not suitable for use in a flammable atmosphere. Do not use this instrument if any flammable gases are present.	This instrument is not suitable for use in a flammable atmosphere. Do not use this instrument if any flammable gases are present.
Max. temperature of parts of the device held by the operator or accessible to the patient	No parts of device with patient/operator contact is energized and remains at ambient temperature	No parts of device with patient/operator contact is energized and remains at ambient temperature
Brightness Control	12V 30W halogen bulb	12V 30W halogen bulb

Conclusion:	Based on non-clinical testing results, the Righton Zoom Slit Lamp NS-2D with option and the data collection and image manipulation software have demonstrated that they are 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Right Medical Products LLC
c/o Ms. Mélanie Deslauriers, B.Sc., MBA
Regulatory Affairs Manager
5325 Cleveland Street, Suite 303
Virginia Beach, VA 23462

AUG 30 2011

Re: K110129
Trade/Device Name: Righton Zoom Slit Lamp with Photo Option, Model NS-2D
Regulation Number: 21 CFR 886.1850
Regulation Name:, AC-Powered Slit-Lamp Biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: August 5, 2011
Received: August 10, 2011

Dear Ms. Deslauriers:

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,

Kesia Alexander

for

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): K110129

Device Name: Righton Zoom Slit Lamp NS-2D with photo option

Indications for Use:

The Righton Zoom Slit Lamp NS-2D with photo 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)

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

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