K042742

OCT 1 8 2004

HEIDELBERG ENGINEERING

510(k) Summary of Safety and Effectiveness

Manufacturer and Submitter

Company Name:	Heidelberg Engineering GmbH
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Contact Person:	Dr. Gerhard Zinser
Date Summary Prepared:	August 30, 2004

Device

Trade/Device Name:	Heidelberg Retina Tomograph II / Rostock Cornea Module (HRT II / RCM)
Common/Usual Name:	Corneal Microscope
Classification Name:	AC-powered Slit-Lamp Biomicroscope
Regulation Number:	21 CR 886.1850
Product Code:	~~HJO~~ MXK
Classification Panel:	Ophthalmic
Classification:	Class II device

Substantial Equivalence

The HRT II / RCM is substantially equivalent to a slit-lamp biomicroscope, a preamendment device, and to the "Nidek Confoscan 2" device, a Class II device that received 510(k) market clearance on October 26, 2001, document control number K012416.

Device Description

The system consists of the HRT II laser scanning camera, the Rostock Cornea Module optics, a mount with headrest, a power supply, and a personal computer. For an examination, the Rostock Cornea Module optics is placed on the laser scanning camera, positioned in front of the patient's eye, in contact with the cornea. The contact surface is a sterile PMMA plate. Images of the anterior segment are acquired, displayed on the computer monitor and stored on the hard drive of the computer from where the images can be retrieved at a later time.

Image formation with the HRT II / RCM is performed by focusing a scanning laser beam to the cornea of the eye under examination and detecting the light reflected or backscattered from the cornea. The light detection system has a confocal optical arrangement, which ensures a small depth of focus. In consequence a two-dimensional image acquired can be considered as an optical section through the corneal layer located at the current focal plane of the optical system. In addition, by moving the focal plane step by step, a sequence of section images at different locations of the focal plane can be acquired. This sequence of images provides a layer-by-layer three-dimensional image. The acquired images are presented to the physician at the computer monitor and stored on the computer's hard disk for later use.

Intended Use

The intended use of the Heidelberg Retina Tomograph II / Rostock Cornea Module is to acquire images of the anterior segment of the eye for the purpose of diagnosing diseases of the anterior segment.

Technological Characteristics Compared to Predicate Device

Comparison of similarities and differences			
	HRT II / RCM	Nidek Confoscan 2 *	Slit-Lamp Biomicro-scope
Indications for use	Imaging and observation of the cellular layers of the anterior segment of the human eye, for the diagnosis and manage-ment of anterior segment diseases.	As a diagnostic tool for observation of the cell layers of the anterior parts of the eye.	Imaging and observation of the anterior segment of the eye for diagnostic purposes.
Corneal contact	Yes. Polymethyl-methacrylate (PMMA) plate.	Not in normal use; how-ever, corneal contact with the microscope lens front surface can occur.	No
Working distance cornea to objective	0 (in contact)	1.98 mm	ca. 50 mm
Corneal contact sensing and warning feature	Not applicable.	Yes	Not applicable.
Pre-sterilized contact surface	Yes. Single use PMMA plate.	No. Microscope lens disinfected according to instructions for use.	Not applicable.
Front surface area	75 mm^2 (PMMA plate)	16.6 mm^2 (microscope lens)	Not applicable.
Focus	Manually variable.	Fixed	Not applicable.
Focus adjustment range	1 mm	Not applicable.	Not applicable.
Adjustment direction	Device is adjusted hori-zontally while the patient is sitting straight in front of the device.	Device is adjusted hori-zontally while the patient is sitting straight in front of the device.	Device is adjusted hori-zontally while the patient is sitting straight in front of the device.
Working position	Horizontal	Horizontal	Horizontal
Optical setup	Confocal microscope	Slit-confocal microscope	Conventional micro-scope.
Type of scanning aper-ture	Point	Slit	Not applicable.
Scanning means	Resonant and galvano-metric scanning motors.	Stepper motor.	Not applicable.
Light source	Class I diode laser, 670 nm wavelength.	Halogen lamp.	Tungsten lamp (typical).
Microscope lens	63x water immersion	40x water immersion	Not applicable.

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Lateral optical resolution	2 microns	1 micron	ca. 10 microns
Optical depth resolution	4 microns	10 microns	ca. 10 microns
Detector	Avalanche photodiode.	CCD camera, monochrome.	Examiner observes image through an ocular, or photographic film, or CCD camera
Lateral field of view	0.4 mm x 0.4 mm	Not known; approximately 0.4 mm x 0.4 mm	Up to 8 mm.
Lateral digital resolution	1 micron/pixel	(Not known.)	Not applicable.
Digital depth resolution	2 micron/pixel	Not applicable.	Not applicable.
Image acquisition time	24 msec	(Not known.)	Not applicable.
Acquisition of three-dimensional images	Yes	No	No
Microscope lens magnification	63x	40x	ca. 16x
Magnification on screen (15", 1024x768 pixels)	300x	500x	ca. 100x
Image storage	Directly into PC RAM, then to PC hard drive.	Directly into PC RAM, then to PC hard drive.	Not applicable.
Image compression method	JPG, loss-free	(Not known.)	Not applicable.
Cell density measurement software	Yes	Yes	No
Corneal profile measurement	Optical sectioning, by shifting the focal plane of the confocal imaging system.	Optical sectioning, by recording of average scatter from different depth locations.	No
Operating and image management software	Heidelberg Eye Explorer	NAVIS	Not applicable.
Physical layout	Lift table, PC, mount with headrest, optical head are separate components.	Lift table, PC, and optical head integrated into one piece.	Lift table, mount with headrest, optical head are separate components.
* According to 510(k) Summary for Nidek Confoscan 2 device, K012416			

Conclusions from Performance Testing

The HRT II / RCM has been tested according to IEC 60601-1 and IEC 60601-1-2, and was found to meet all requirements. The system is a laser product of Class 1 according to 21 CFR Part 1040 Section 1040.10 and IEC 60825-1:1993+A2:2001.
The evaluation of the device and comparison of acquired images resulted in substantial equivalence to the predicate devices with respect to intended use, technological characteristics, and safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 2004

Heidelberg Engineering GmbH
c/o TUV America, Inc.
Mr. Stefan Preiss
1775 Old Highway 8
New Brighton, MN 55112-1891

Re: K042742
Trade/Device Name: Heidelberg Retina Tomograph II / Rostock Cornea Module (HRT II / RCM)
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered Slit-Lamp Biomicroscope
Regulatory Class: Class II
Product Code: MXK
Dated: September 30, 2004
Received: October 4, 2004

Dear Mr. Preiss:

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) 594-4613. 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/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, 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): K042742

Device Name: Heidelberg Retina Tomograph „" / Rostock Cornea Module

Indications for Use: Imaging and observation of the cellular layers of the anterior segment of the human eye, for the diagnosis and management of anterior segment diseases.

Prescription Use ___X___ (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)

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

510(k) Number K042742