JAN 2 8 2005

K041841

510(K) SUMMARY

Substantially equivalent

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General Information

Applicant's Name and Address:	OCULUS Optikgeräte GmbH Münchholzhäuser Straße 29 D-35582 Wetzlar
Date of Summary:	17 June 2004
Owner/Operator Number:	8010318
Contact person:	Mr. Joerg Iwanczuk Product Manager

Device Name

Trade Name:	Pachycam
Class:	Class II
Classification Name:	Scheimpflug Camera
Product Code:	MXK Anterior Eye-Segment Analysis System
Regulation Number:	886.1850

Predicate Devices

The Pachycam is claimed to be substantially equivalent to the following currently market device:

Pentacam, Scheimpflug Camera, OCULUS Optikgeraete GmbH, Germany; K 030179

Device Description:

The Pachycam is a non-invasive, diagnostic system created to take photos of the anterior segment of the eye, portable and AC powered. The system is based on the Scheimpflug Principle for Slit Image photography. The device consists of a measurement unit, power supply and a CPU. The measuring system uses blue light (UV-free) given to a slit to illuminate the eye, and a CCD-Camera for photography. The device takes a series of images of the anterior segment of the eye from one fixed location (180°) and analyses one, selected by software.

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Product Comparison

	OCULUS Pentacam	New device, Pachycam
Manufacturer	OCULUS Optikgeräte GmbH	OCULUS Optikgeräte GmbH
Measuring Principle	Scheimpflug Principle for Slit Image photography	Scheimpflug Principle for Slit Image photography
Optical	Please refer to the detailed description	
Observation Illumination	Infrared LED 800nm for pupil illumination	Infrared LED 800nm for pupil illumination
Flash Output Illumination	Blue LED Light (UV-free) 475nm, max. 2.5W Power Input	Blue LED Light (UV-free) 455nm, max. 2.5W Power Input
Camera	CCD-Camera	CCD-Camera
Display	Data digital, displayed on a CPU	Data digital, displayed on a CPU
Image resolution	800 x 600 pixel	640 x 480 pixel
Measuring points	500 per image	600 per image
Image size	5.6 x 4.5mm	4.8mm x 3.6mm
Photographic range	Eligible 0 to 360° automatically	Fixed slit position in 180°
Photographic Series	1 to 50 photos	5 images
Exposure Control	Fixed during calibration, max 2.5Wsec. Power input	Fixed during calibration, max 2.5Wsec. Power input
Slit Length	14mm fixed	5mm fixed
Illumination time during alignment	Limited to 300 seconds	Limited to 300 seconds
Where used	Hospital, ambulance	Hospital, ambulance
Intended use	Please refer to the detailed description	
Sterilisation	Please refer to the detailed description	
Materials	Housing is made of steel, the back is made of Polyurethane, specially treated, not	Housing is made of Polyurethane, specially treated, not inflammable

	inflammable	
Mechanical safety	Please refer to the detailed description	
Power supply	External, 110/220 VAC, 50/60Hz	External, 110/220 VAC, 50/60Hz
Power Consumption	50VA	27 VA
Power requirement	25 VDC 2A / 5 VDC 2A	9 VDC, 3A
Weight	9 kg	1 kg

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Basics for Substantial Equivalence

The systems utilize the same or similar Operating System. It contains:

- an optical system,
- a source of illumination for observation and photography,
- a CCD-Camera as photographic medium,

Both systems have the same intended use, to measure the anterior eye segment

Both systems use the same device features like a

- head stabilizing device
- external fixation target
- joy stick for control mechanism.

Both systems are considered "Non Invasive" as defined in 21 CFR §812.3(k) and considered not to be a "Significant Risk Device" as defined in 21 CFR §812.3(m)

Indications for Use

Intended Use:

The Pachycam is designed to photograph the eye and take Scheimpflug images of the anterior segment of the eye to evaluate the thickness of the cornea. The implanted keratometer measures the central radii of the cornea.

Safety

The Pachycam is a non-invasive diagnostic system, which contacts the patient only on his/her chin and forehead. The Pachycam does not present or pose any new or additional effects for risk on the safety prescribed intended uses. The light output is of an eye safe intensity and wavelength. The electrical safety requirements for medical devices are met. The Pachycam is proven effective for its intended uses through internal company studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2005

OCULUS Optikgeräte GmbH
c/o Mr. Joerg Iwanczuk
Dutenhofen
Münchholzhäuser Strasse 29
D-35582 Wetzlar
Germany

Re: K041841
Trade/Device Name: Pachycam Scheimpflug Camera
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slitlamp biomicroscope
Regulatory Class: Class II
Product Code: MXK
Dated: December 23, 2004
Received: January 4, 2005

Dear Mr. Iwanczuk:

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

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10 Intended use

510(k) number: k 041841

Device name: Pachycam Scheimpflug Camera

Indications For Use:

The Pachycam is designed to photograph the eye and take Scheimpflug images of the anterior segment of the eye to evaluate the thickness of the cornea. The implanted keratometer measures the central radii of the cornea.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510 (k) Number K041841 (Optional Format 3-10-98)