

NOV 25 2009

510(K) Summary	CLARITY MEDICAL SYSTEMS, INC.
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Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

Device Name: RetCam II Ophthalmic Imaging System
RetCam 3 Ophthalmic Imaging System
RetCam Shuttle Ophthalmic Imaging System
RetCam Portable Ophthalmic Imaging System

Common Name(s): Ophthalmic Imaging System

Classification Name(s): Ophthalmic Camera

Manufacturer: Clarity Medical Systems, Inc.

Reg. Number: 2952489

Address: 5775 W. Las Positas Blvd.
Pleasanton, CA 94588-4084

Telephone: (925) 463-7984

Classification(s):

Device Class: Class II

Classification Panel: Ophthalmology

Product Code(s): HKI

Equivalent Predicate Devices: RetCam II Ophthalmic Imaging System, K081858
RetCam 3 Ophthalmic Imaging System, K081858
RetCam Shuttle Ophthalmic Imaging System, K081858
RetCam Portable Ophthalmic Imaging System, K083771

Device Description:

RetCam Ophthalmic Imaging Systems utilize a digital camera in a handpiece with multiple field of view lenses to capture color ophthalmic digital images including retinal, corneal, and external images. An on board computer (RetCam II and RetCam 3) or laptop computer (RetCam Shuttle and RetCam Portable) is used to store, view, retrieve, and export the digital ophthalmic images. A standard Halogen light source is used in all RetCam configurations to provide illumination to the eye through the handpiece. An optional Fluorescein light source is also available with the RetCam II and RetCam 3 configurations. Light intensity, camera focus, and image capture are controlled by the use of a footswitch on all configurations and can also be controlled by a keyboard on the RetCam II and RetCam 3 consoles. Console monitors are provided with the RetCam II and RetCam 3 configurations for viewing images. The laptop monitor is used for viewing images with the RetCam Shuttle and RetCam Portable. Proprietary software is installed on the computers to capture, store, view, retrieve, and export ophthalmic images.

Indication for Use:

- General ophthalmic imaging including retinal, corneal, and external imaging.
- Photodocumentation of pediatric ocular diseases including retinopathy of prematurity (ROP).
- Screening for Type 2 pre-threshold retinopathy of prematurity (ROP) (zone 1, stage 1 or 2, without plus disease, or zone 2, stage 3, without plus disease) or treatment-requiring ROP, defined as Type 1 ROP (zone 1, any stage, with plus disease; zone 1, stage 3 without plus disease; or zone 2, stage 2 or 3, with plus disease) or threshold ROP (at least 5 contiguous or 8 non-contiguous clock hours of stage 3 in zone 1 or 2, with plus disease)* in 35-37 week postmenstrual infants.

***References:**

1. Cryotherapy for Retinopathy of Prematurity Cooperative Group. Multicenter trial of cryotherapy for retinopathy of prematurity: preliminary results. Archives of Ophthalmology 1988; 106(4):471-479.
2. Early Treatment for Retinopathy of Prematurity Cooperative Group. Revised indications for the treatment of retinopathy of prematurity: results of the Early Treatment for Retinopathy of Prematurity Randomized Trial. Archives of Ophthalmology 2003; 121(12):1684-1694.

Clinical Performance Data:

Chiang, et. al. (Telemedical Retinopathy of Prematurity Diagnosis Accuracy and, Reliability, and Image Quality; Archives of Ophthalmology; 2007;125(11):1531-1538) reported the results of a prospective trial to measure the accuracy, reliability, and image quality of RetCam wide-field digital images to screen for ROP. Eyes from 67 consecutive infants underwent RetCam wide-field digital retinal imaging by trained neonatal nurses using a standard protocol of 3 images per eye and the 130 degree lens. The infants were 31 to 33 weeks and/or 35 to 37 weeks postmenstrual age (PMA).

Images were interpreted by three expert retinal specialist graders who provided a diagnosis and evaluation of image quality. Findings were compared with a reference standard of binocular indirect ophthalmoscopy (BIO) by experienced pediatric ophthalmologists. The target condition (referral warranted disease-the presence of Type 2 pre-threshold or worse ROP) in this study that supports the use of RetCam as an ROP screening tool is Type 2 Pre-threshold ROP (Zone 1, Stage 1 or 2, without plus disease, or Zone 2, Stage 3, without plus disease) or treatment requiring ROP (Zone 1, any stage, with Plus disease; Zone 1, stage 3 without plus disease; or Zone 2, stage 2 or 3 with Plus disease) or threshold ROP (at least 5 contiguous or 8 non-contiguous clock hours of stage 3 in zone 1 or 2, with plus disease) at 35-37 weeks PMA.

Sensitivity and Specificity Statistics by Grader

Grader	Performance For Type 2 Threshold ROP Or Worse			
	Sensitivity	~95% CI for Sensitivity	Specificity	~95% CI for Specificity
A	1.0 (26/26)	(0.868, 1.0)	0.883 (83/94)	(0.802, 0.933)
B	1.0 (26/26)	(0.868, 1.0)	0.851 (80/94)	(0.765, 0.909)
C	1.0 (26/26)	(0.868, 1.0)	0.851 (80/94)	(0.765, 0.909)

Image Quality

Before providing a diagnosis for each image set, the 3 retinal specialist graders assessed the technical quality of the images for “adequate”, “possibly adequate” or “inadequate”. Each of them found that images taken at 35-37 weeks PMA by trained NICU nurses were technically “adequate” or “possibly adequate” at a rate of 93.3% to 100%.

Conclusion

The Clinical Performance data note above was gathered using the RetCam II Ophthalmic Imaging System and supports the revised Indication for Use for the RetCam II Ophthalmic Imaging System, the RetCam 3 Ophthalmic Imaging System, the RetCam Shuttle Ophthalmic Imaging System, and the RetCam Portable Ophthalmic Imaging System.

Company Contact:

Gary A. Seeger
Vice President, Quality Assurance and Regulatory Affairs
Clarity Medical Systems, Inc.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

NOV 25 2009

Clarity Medical Systems, Inc
c/o Mr. Gary A. Seeger
Vice President, Quality Assurance and Regulatory Affairs
5775 W. Las Positas Blvd.
Pleasanton CA 94588

Re: K090326

Trade/Device Name: RetCam II, RetCam 3, RetCam Shuttle, RetCam Portable
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic camera
Regulatory Class: Class II
Product Code: HKI

Dated: September 10, 2009

Received: September 14, 2009

Dear Mr. Seeger:

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 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

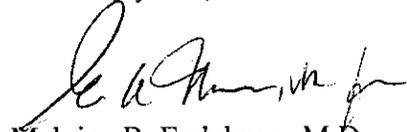
Mr. Gary A. Seeger

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: K090326

Device Name(s): RetCam II Ophthalmic Imaging System
RetCam 3 Ophthalmic Imaging System
RetCam Shuttle Ophthalmic Imaging System
RetCam Portable Ophthalmic Imaging System

Indications for Use:

Each and all above listed RetCam Systems are indicated for:

- General ophthalmic imaging including retinal, corneal, and external imaging;
- Photodocumentation of pediatric ocular diseases including retinopathy of prematurity (ROP).
- Screening for Type 2 pre-threshold retinopathy of prematurity (ROP) (zone 1, stage 1 or 2, without plus disease, or zone 2, stage 3, without plus disease) or treatment-requiring ROP, defined as Type 1 ROP (zone 1, any stage, with plus disease; zone 1, stage 3 without plus disease; or zone 2, stage 2 or 3, with plus disease) or threshold ROP (at least 5 contiguous or 8 non-contiguous clock hours of stage 3 in zone 1 or 2, with plus disease)* in 35-37 week postmenstrual infants.

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Prescription Use X Or Over the Counter Use

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)



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

510(k) Number K090326