APR 2 0 2011

510(K) Summary K102859	CLARITY MEDICAL SYSTEMS, INC.

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

Device Name: RetCam 3 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 Device: RetCam 3 Ophthalmic Imaging System, K090326, K081858
RetCam II Ophthalmic Imaging System, K090326, K081858

Device Description:

The RetCam 3 Ophthalmic Imaging System utilizes 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 is used to store, view, retrieve, and export the digital ophthalmic images. A standard Halogen light source is used to provide illumination to the eye through the handpiece. An optional Xenon light source is also available with the RetCam 3 to facilitate imaging with fluorescein angiography. Light intensity, camera focus, and image capture are controlled by the use of a RetCam 3 footswitch and can also be controlled by a keyboard on the RetCam 3 consoles. A console monitor is provided with the RetCam 3 for viewing images. Proprietary software is installed in the computer to capture, store, view, retrieve, and export ophthalmic images.

A device modification to the RetCam 3 is being made to replace the Xenon light source module with an LED light source module. Third party testing has been performed and formal certification has been obtained verifying compliance with the applicable IEC 60601 electrical safety and electromagnetic compatibility standards. Bench testing has verified comparable safe maximum light irradiance output of the Xenon and LED light source modules. Bench testing has verified comparable fluoresce dye responses to the Xenon and LED light sources.

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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

	Performance For Type 2 Threshold ROP Or Worse			
Grader	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)

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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%.

Animal Studies

Image results were obtained using an approved LyChron non-clinical study protocol. The stated purpose of the protocol was to provide a controlled image comparison of both the Xenon and LED FA light sources in the same animal model. The images obtained with the LED FA light source are substantially equivalent in contrast and detail to images obtained using the Xenon FA module.

Bench Testing

IEC 60601-1 electrical safety testing, IEC 60601-1-2 EMC testing, and maximum light irradiance testing were conducted in accordance with established protocols. All testing demonstrated compliance with necessary electrical, EMC, and light safety requirements.

Conclusion

There are slight differences between the Xenon and LED generated light sources worth noting;

- FA light source - Light output at the handpiece is in the same wavelength. Though the values not are identical they have no adverse safety impact.
- FA Light Irradiance - Irradiance levels also not identical but both Xenon and the new LED light source meet ACIGH TLV specifications and have no adverse safety impact.
- FA Module software – The LED FA light source has added software controls to hardware controls whereas the Xenon based light source required no software. Accordingly, all appropriate V&V activities are complete. Safety has been demonstrated as not adversely impacted.

The Clinical Performance data note above was gathered using the RetCam II Ophthalmic Imaging System and supports the Indication for Use for both the RetCam II Ophthalmic Imaging System and the RetCam 3 Ophthalmic Imaging System as cleared in K090326.

Company Contact:

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

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

Clarity Medical Systems, Inc.
c/o Gary A. Seeger
Vice President, Quality Assurance and Regulatory Affairs
5775 West Las Positas Blvd, St. 200
Pleasanton, CA 94588

APR 20 2011

Re: K102859
Trade/Device Name: RetCam3 Ophthalmic Imaging System
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic camera
Regulatory Class: Class II
Product Code: HKI
Dated: March 15, 2011
Received: March 16, 2011

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. 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

510(k) Number: K102859

Device Name(s): RetCam3 Ophthalmic Imaging System

Indications for Use Statement(s) for each and all above listed RetCam Systems:

- 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 K102859