

Fundus Photo, LLC
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K093071

510(k) Summary

NOV 17 2010

Name of device: Fundus Photo Digital Imaging System Model CFD-440

Common or usual name: Camera, Ophthalmic (AC Powered)

Classification Name: Ophthalmic Camera (per 21 CFR 886.1120)

Product Code: HKI,
Subsequent Product Code: NFF, NFG

Submitter: Fundus Photo, LLC
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Saint Louis, MO 63103
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Contact Person: Dale Brodsky
Date Prepared: September 09, 2010

Predicate Device

<u>Trade Name</u>	<u>Manufacturer</u>	<u>510 (k)</u>
Zeta Diagnostic Retinal Imaging System	Zeta Development Laboratories	K022164

Intended Use

The Fundus Photo Digital Imaging System Model CFD-440 Model is intended to capture, archive and display digital images of the retina and surrounding areas of the eye.

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Device Description

The Fundus Photo Digital Imaging System Model CFD-440 is an automated imaging device used in conjunction with an ophthalmic fundus camera that requires minimal intervention during the capture of an image. The system is simple to use and requires nominal training for a user to become proficient. Like the predicate device, the Fundus Photo Digital Imaging System Model CFD-440 is an accessory attachment comprised of a digital imaging camera or cameras, computer hardware and software platform intended to capture, store, archive, and display images acquired by the fundus camera. Thus the Fundus Photo Digital Imaging System Model CFD-440 has the same intended use and indications as the predicate device.

The CFD-440 utilizes a universal adapter design to attach with various fundus camera models. The following table illustrates examples of the fundus camera model with corresponding current Canon Digital EOS camera used for each model listed.

Fundus Camera Name/Model/510(k)#	Digital Camera Model
Canon CR-1 Mark II (K090466)	Canon EOS 50D
Canon CR-1 (K080883)	Canon EOS 50D
Canon CR5-45NM (K941234)	Canon EOS XSi
Canon CR6-45NM (K980246)	Canon EOS XSi
Canon CR-DGi (K031629)	Canon EOS 5D Mark II
Canon CF-1 (K063717)	Canon EOS 5D Mark II
Canon CF-60DSI (K041546)	Canon EOS 5D Mark II
Kowa FX-500 (K954780)	Canon EOS 5D Mark II

Substantial Equivalence

Principles of Operation

The Fundus Photo Digital Imaging System Model CFD-440 and the predicate device have the same intended use: capture, archive, and display digital images of the retina and surrounding areas of the eye. The Fundus Photo Digital Imaging System Model CFD-440 and predicate device have equivalent principles of operation and technological characteristics. Each of the devices is a digital ophthalmic imaging system attached to an FDA-approved fundus camera. The user views the patient's retina through the existing fundus camera or external display. The fundus camera acquires and transfers to the capture camera (film or digital, CMOS or CCD) to display images of the retina and surrounding areas of the eye. These digitized images are then archived for future use and record documentation.

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Hardware

The Fundus Photo Digital Imaging System Model CFD-440 and predicate device are operated by a PC with keyboard and a hand operated mouse. While there may be some minor differences in capture camera devices (film or digital, CMOS or CCD), types of processor (i.e. Intel or AMD), memory and software platform, these minor differences do not raise any new issues of safety or effectiveness.

Software

The Fundus Photo Digital Imaging System Model CFD-440 and the predicate device have the same basic software functions: image capture, display, storage, analysis and retrieval.

The Fundus Photo system has additional features: Daily activity log, gamma and sharpening image control, automatic storage to hard drive of captured images, image enhancement control from the print preview, ability to retrieve deleted patient data and images, export for email, record of the photographer name in addition to the doctor name, support for displaying Adobe, Excel and Word documents and support for network and external hard drive archiving.

Fundus Photo has performed software verification, validation and performance tests. The results indicate that the Fundus Photo Digital Imaging System Model CFD-440 is substantially equivalent to the software standards exhibited by the predicate device.

Performance Characteristics

The Fundus Photo Digital Imaging System Model CFD-440 is an accessory attachment comprised of the following components: digital camera(s), computer, monitor, adapter, cables, instructions for use and image processing software. This complete system provides capture and hardware capabilities used in conjunction with an ophthalmic fundus camera or similar capture device that acquires images of the retina and surrounding areas of the eye. These images are then transferred from the digital camera to the computer system where the images are stored to the hard drive automatically. Images can be viewed, modified, transferred or printed. *The Fundus Photo Digital Imaging System Model CFD-440 does not contact the patient.*

The Fundus Photo Digital Imaging System Model CFD-440 user software interface allows acquired images from the fundus camera to be captured, displayed, stored and retrieved. Image focus and orientation of the retina and surrounding areas of the eye are controlled with the fundus camera optics by the user in the same manner as when using traditional film camera backs. With verification and monitoring by the user, the software allows the user to monitor the capture process, verifying the device is operating correctly. Images acquired by the fundus camera are then, in turn, captured by the Fundus Photo Digital Imaging System Model CFD-440 and stored automatically

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as individual images on the hard drive of the computer to be displayed or recalled electronically as the user requires.

Conclusion

The Fundus Photo Digital Imaging System Model CFD-440 has the same intended use, indications and equivalent principals of operation to the predicate device. The Fundus Photo Digital Imaging System Model CFD-440 has similar technological characteristics (operation, hardware and software) to the predicate device.

The minor differences between the Fundus Photo Digital Imaging System Model CFD-440 product and those of the predicate device do not raise any new questions of safety or effectiveness. Thus, the Fundus Photo Digital Imaging System Model CFD-440 is substantially equivalent to the Zeta Diagnostic Retinal Imaging System.



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

Fundus Photo, LLC
c/o Mr. Dale Brodsky
President
3015 Locust Street
Saint Louis, MO 63103

NOV 17 2010

Re: K093071

Trade Name: Fundus Photo Digital Imaging System Model CFD-440
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic camera
Regulatory Class: Class II
Product Code: HKI
Dated: September 9, 2010
Received: September 13, 2010

Dear Mr. Brodsky:

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.

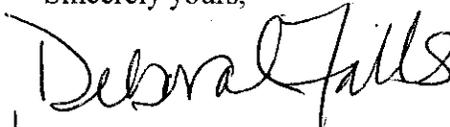
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "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,



Malvina B. Eydelman

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

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Indications for Use Statement

510(k) Number (if Known) K093071

Device Name: Fundus Photo Ophthalmic Digital Imaging System Model CFD-440

Indications for Use:

The Fundus Photo Digital Imaging System Model CFD-440 Model is intended to capture, archive, and display digital images of the retina and surrounding areas of the eye.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use or Over-the-counter Use


(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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