K020888

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NOV 7 2002

Visual Pathways

A New Vision in Eye Care

APPENDIX D

510(k) Summary

This summary of premarket notification safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92(c).

Date Prepared: August 1, 2002

Applicant:
Visual Pathways, Inc.
334 White Spar Road
Prescott, AZ 86303-4238
(928) 778-5002 – Voice
(928) 778-5004 – FAX

Contact:
Mr. Gary F. Buck
(928) 778-5002 – Voice
(928) 778-5004 – FAX

Registration: K020888

Device Name:
Proprietary Name—Fundus AutoImager™
Common Name—AC Powered Ophthalmic Camera
Classification Name—Ophthalmic Camera (21 CFR 886.1120)

Note: This classification name is in accordance with FDA's publication "Classification Names for Medical Devices and In-Vitro Diagnostic Products" (FDA 95-4246). In addition, 21 CFR 886.1120 is cited in this publication as the corresponding regulation.

Legally Marketed Device for Claiming Substantial Equivalence:

Manufacturer	Device Name	510(k) Number
Carl Zeiss Jena GmbH	FF450(plus) VISUPAC	K011877
Topcon Medical Systems	ImageNet Digital Ophthalmic Imaging System	K870039

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Intended Use: The Fundus AutoImager™ is an automated ocular fundus imaging device that allows for the rapid capture, storage, manipulation and transmission of images of the eye, especially the retina area, as an aid in diagnosing or monitoring diseases of the eye that may be observed and photographed. The Fundus AutoImager requires minimal operator training and intervention during the imaging process. It is intended for use with patients for whom examination of the fundus for pathologies is requested.

The Fundus AutoImager is designed as a film-less imaging system, utilizing a high-resolution digital camera that allows for convenient storage and transmission of images.

Device Description: The Fundus AutoImager utilizes video cameras for alignment, focus and tracking of the patient's pupils and a high-resolution (1k x 1k) charge-coupled device (CCD) camera for focus and tracking of the fields of interest on the patient's fundus. The system acquires stereo pairs of images that are displayed on a video monitor. The operator can select for imaging in monochrome or color and the images can be stored to disk, printed, or sent to a remote location via the Internet.

All of the aligning and focusing procedures are performed using barely visible infrared illumination. With such illumination, the patient's pupils do not constrict and for all but patients with unusually small natural pupils, no artificial dilation is required.

Technological Characteristics/Substantial Equivalence:

The indications or intended uses of the Visual Pathways, Inc. Fundus AutoImager and legally marketed predicate devices such as the Zeiss FF450 VISUPAC system (K011877) and Topcon Medical Systems' ImageNet Digital Ophthalmic Imaging System (K870039) are intended to capture and store images of the retina taken by a fundus camera. The Fundus AutoImager is an automated imaging device that is intended to capture, store, manipulate and transmit images of the fundus. The Fundus AutoImager requires minimal operator training and intervention during the imaging process. It is intended for use for patients for whom examination of the fundus for pathologies is requested. Some predicate devices are likewise comprised of fundus cameras and computer hardware and software systems intended to capture, store, manipulate and transmit images of the fundus. Thus, the Fundus AutoImager ophthalmic camera has the same intended use and indications as the predicate devices.

The same technological characteristics of the Fundus AutoImager are also present in many legally marketed ophthalmic cameras.

The Fundus AutoImager and the predicate devices have similar general principles of operation and technological characteristics. Each of the devices is an ophthalmic camera. The user views the patient's retina through a fundus camera. A light source is used to illuminate the retina and the images formed are captured by the camera. The images are then digitized and stored. Successive images are taken to permit viewing a larger area of the retina. With some predicate devices, the stored images may be viewed on a monitor.

The technological differences between the Fundus AutoImager and its predicate devices are the degree of automation of the Fundus AutoImager ophthalmic camera, including its auto-pupil alignment and focus, auto-fundus alignment and focus, auto-retinal field accession, and auto-image collection and mosaicing. The Fundus AutoImager also differs from some of the predicate devices in its image storage system and the media on which the images may be captured, that is, digital electronic display versus film or printed image. However, these differences do not raise any new questions of safety or effectiveness. The Fundus AutoImager uses dedicated cameras and an automated illumination system for imaging the pupil and the fundus. Predicate devices use fundus cameras that rely upon manual targeting, focusing and image capture.

Based on the reasons provided, the Fundus AutoImager is substantially equivalent to legally marketed predicate devices.

Conclusions:

Per 21 CFR Section 807.92(b)(3), we have clinically evaluated the performance of the Fundus AutoImager™, in conjunction with our marketing partner Inoveon Corp., Oklahoma City, OK and their Chief Scientific Officer, Stephen Fransen, M.D. Dr. Fransen, a board certified ophthalmologist and retinal specialist, directed the evaluation, comparing the performance characteristics of the Fundus AutoImager with the Zeiss FF450 fundus camera. The evaluation, among other things, considered the quality of images obtained, ease of operation, time required to access a single stereo pair of images, time to acquire multiple field stereo imaging (such as the diabetic retinopathy NIH standard, sever field stereo imaging), safety of patient and operator. Dr. Fransen and his team acquired multiple field images on approximately one hundred thirty patients. This number included both dilated and undilated conditions. From their evaluation of the Fundus AutoImager and the images produced, we have confirmed that the Fundus AutoImager is a product that incorporates some novel designs in both software and hardware to achieve

Visual Pathways, Inc.

improved performance through more automated, faster and simpler operation. The comparison of the Fundus AutoImager with predicate devices demonstrates substantial equivalence with those devices. At the same time, the Fundus AutoImager presents no new issues in regard to patient or operator safety, or effectiveness.

Signed: _____ Date: 5/7/02

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 7 2002

Visual Pathways, Inc.
c/o Gary F. Buck
334 White Spar Road
Prescott, AZ 86303

Re: K020888
Trade/Device Name: Fundus AutoImager™
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: August 8, 2002
Received: August 9, 2002

Dear Mr. Buck:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

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

PreMarket Notification 510(k)
Fundus AutoImager™
Visual Pathways, Inc.

STATEMENT OF INDICATIONS FOR USE

The Fundus AutoImager™ is an automated ocular fundus imaging device that allows for the rapid capture, storage, manipulation and transmission of images of the eye, especially the retina area, as an aid in diagnosing or monitoring diseases of the eye that may be observed and photographed.

This device will also bear the prescription legend:
"Caution: Federal law restricts the use of this device on the order of a physician."

Prescription Use _____
(Per 21 CFR 801.109)

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

510(k) Number K020588