Section 05
510(k) Summary (Cont.)

510(k) Notification K 113451

GENERAL INFORMATION

Applicant:
Nidek Co., Ltd 34-14, Maehama, Hiroishi-cho
Gamagori, Aichi 443-0038 Japan
Phone: +81-533-67-8901 Fax: +81-533-67-6628

Contact Person:
Enrico Bisson
Quality and Regulatory Affairs Manager
Nidek Technologies srl
Via dell'Artigianato, 6/A I - 35020 Albignasego (Padova)
tel. +39 049 8629200 fax +39 049 8626824
E-mail: enricobisson@nidektechnologies.it

Date Prepared: October 31, 2011

DEVICE INFORMATION

The Non-Mydriatic Auto Fundus Camera AFC-330 with Image Filing Software NAVIS-EX ("AFC-330 with NAVIS-EX") is a conventional non-mydriatic auto fundus camera. The AFC-330 with NAVIS-EX captures fundus images using a built-in colour CCD camera without the use of mydriatic agents. With this single device, registration of patient information, image capture, and viewing of captured images are possible.

By connecting a personal computer (PC) to the device via a LAN and installing the NAVIS-EX image filing system software, images captured by this device can be transferred to the PC and viewed and managed on the PC.

Classification:
21 CFR§886.1120, Class II

Product Code:
HKI

Subsequent Classification:
21 CFR 892.2010 class I; 21 CFR 892.2020 class I

Subsequent product codes:
NFF, NFG

Trade Name:
Non-Mydriatic Auto Fundus Camera AFC-330 with Image Filing Software NAVIS-EX

Generic/Common Name:
Camera, Ophthalmic, Ac-Powered

K113451

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PREDICATE DEVICES
Nidek NM-1000 (K014274)
Carl Zeiss Meditec FF450 with Fundus Camera and VISUPAC System (K011877)
Nidek Technologies Orion (K070231)

INDICATIONS FOR USE
The Non-Mydriatic Auto Fundus Camera AFC-330 with Image Filing Software NAVIS-EX is intended to capture, display, store and manipulate images of the retina and the anterior segment of the eye, to aid in diagnosing or monitoring diseases of the eye that may be observed and photographed.

PRODUCT DESCRIPTION
The Non-Mydriatic Auto Fundus Camera AFC-330 with Image Filing Software NAVIS-EX ("AFC-330 with NAVIS-EX") is a conventional fundus camera.
Regarding the alignment, an observation light irradiates the patient's fundus. The light reflected from the patient's fundus is received by the CCD camera for observation.
Regarding the image capturing, the light emitted from a xenon flash lamp is guided to the main body and the light is made coaxial with the observation light. The light then irradiates the patient's fundus. The light reflected from the patient's fundus is received by the CCD camera for capturing .
AFC-330 with NAVIS-EX allows the operator to conduct the observation of the retina with reduced time, an increased usability, thanks to some improved features.

SUBSTANTIAL EQUIVALENCE
AFC-330 with NAVIS-EX represents a modification to a cleared device, the Nidek NM 1000. The principle modification is the introduction of some functions:

- Anterior eye image capturing mode
- Stereo image capturing mode
- Panorama Photography Mode
- Eyelid and required pupil diameter detection
- Image filing software

The image filing software NAVIS-EX represents a modification to another cleared devices, the Carl Zeiss Meditec FF450 with Fundus Camera and VISUPAC System and the Nidek Technologies Orion with NAVIS software, allowing the user to export, manage and process the images acquired by the Non-Mydriatic Auto Fundus Camera AFC-330.

AFC-330 with NAVIS-EX is substantially equivalent to the predicate devices with regard to design, function, safety and technological and performance characteristic, intended use.

Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the proposed AFC-330 with NAVIS-EX is substantially equivalent to the predicate devices.

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TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench testing was conducted on the AFC-330 with NAVIS-EX to support a determination of substantial equivalence to the predicate devices. The performance testing included the following tests:

- Electrical and mechanical safety testing
- Electromagnetic compatibility testing
- Light burden testing
- Verification and validation testing

SUMMARY

The collective performance testing results demonstrate that AFC-330 with NAVIS-EX is substantially equivalent to the predicate devices.

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

Nidek Technologies Srl
c/o Mr. Enrico Bisson
Quality and Regulatory Affairs Manager
Via dell'Artigianato, 6/A
Albignasego (Padova)
IT 35020

MAY - 8 2012

Re: K113451
Trade/Device Name: Non-Mydriatic Auto Fundus Camera AFC-330 with Image Filing Software NAVIS-EX
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: II
Product Code: HKI, NFF, NFG
Dated: April 24, 2012
Received: April 25, 2012

Dear Mr. Bisson:

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

Section 04
Indications for Use Statements

INDICATIONS FOR USE

510(k) Number (if known): **K113451**

Device Name: Non-Mydriatic Auto Fundus Camera AFC-330 with Image Filing Software NAVIS-EX

Indications for Use: The Non-Mydriatic Auto Fundus Camera AFC-330 with Image Filing Software NAVIS-EX is intended to capture, display, store and manipulate images of the retina and the anterior segment of the eye, to aid in diagnosing or monitoring diseases of the eye that may be observed and photographed.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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