APR 17 2002

K014274

SECTION 17

510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) SUMMARY
Nidek Non-Mydriatic Fundus Camera Model NM-1000

1. SUBMITTER INFORMATION

A.	Company Name:	Nidek Incorporated
B.	Company Address:	47651 Westinghouse Drive. Fremont, CA 94539-7474
C.	Company Phone: Company Fax:	(510) 353-7722 (510) 226-5750
D.	Contact Person:	Mr. Hiro Matsuzaki Quality Assurance Manager Nidek Incorporated
E.	Date Summary Prepared:	December 21, 2001

2. DEVICE IDENTIFICATION

A.	Classification Name:	Ophthalmic Camera (AC-Powered)
B.	Trade/Proprietary Name:	Nidek Non-Mydriatic Fundus Camera Model NM-1000
C.	Device Classification:	Class II (per 21 CFR 886.1120)
D.	Product Code:	HKI

3. SUBSTANTIAL EQUIVALENCE

The Nidek Incorporated NM-1000 device is of comparable type and is substantially equivalent to the following predicate device:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Canon CR6-45NM Non-Mydriatic Retinal Camera	Canon USA, Inc.	K980246	May 6, 1998

4. DEVICE DESCRIPTION

Nidek Co., Ltd. has developed the Model NM-1000, which is a stationary-type ophthalmic non-mydriatic fundus camera. Without using 35mm or instant films, this fundus camera incorporates a full digital video capturing system with memory functions, and can transfer captured images to a personal computer. The NM-1000 is designed to deliver its full performance as a fundus camera specializing in digital video capturing as a stand-alone unit or in combination with an image filing system.

In the same manner as other conventional fundus cameras, the Model NM-1000 fundus camera projects the fundus using invisible infrared beams of light during alignment and monitors patient's eye using an infrared video system which does not burden the patient's eye. As a high-sensitivity CCD chip captures an image during use, only a very small amount of flash is used as compared to the flash intensity used with instant film, therefore only giving a mild shock to the patient. The Model NM-1000 fundus camera can capture images with a very low amount of light as compared to a conventional fundus camera that uses an instant film.

The Model NM-1000 fundus camera design incorporates the camera unit and power unit into a single integrated table-top unit. During alignment, the camera displays (on the video monitor) patient ID number, as well as focusing functions such as a working distance detection spot and the focusing indicator.

The captured image is temporarily saved in the camera unit just after being captured, and is displayed as a color still image on the video monitor in real time. This allows the operator to immediately judge if the captured image is satisfactory or not. Furthermore, a large-scale 6.4-inch LCD display is used to enhance ease of operation.

Various terminals are provided to allow the operator to output and use the temporarily saved images for various purposes. The Model NM-1000 fundus camera can

interface with other devices through the use of a USB port, RGB analog output and composite video output (NTSC) connections.

5. INTENDED USE

The Nidek Non-Mydriatic Fundus Camera Model NM-1000 is intended for use in capturing images of the retina and the anterior segment of the eye. This fundus camera can transfer images to a personal computer.

6. TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Nidek Non-Mydriatic Fundus Camera Model NM-1000 and the predicate device has been performed, and the results are summarized in the table below. The results of this comparison demonstrate that the Nidek Non-Mydriatic Fundus Camera Model NM-1000 has the same basic technological characteristics as the predicate device and is equivalent to the marketed predicate device. The differences between the Nidek Non-Mydriatic Fundus Camera Model NM-1000 and the predicate device are insignificant and do not affect the safety or effectiveness of the device.

PREDICATE DEVICE COMPARISON CHART		
	Nidek Non-mydriatic Fundus Camera Model NM-100	**Canon CR6-45NM K980246**
Indications For Use	The Nidek NM-1000 is an ophthalmic camera that is indicated for use in capturing images of the retina and the anterior segment of the eye.	The CR6-45NM is indicated for use in taking pictures of the retina of the human eye.
CAMERA:		
Saved Image Format	Nidek format (extension NFC) or Tiff format (extension TIF)	JPEG, TIF, DICOM
Picture angle	45°	45°
Working distance	43.3 mm (from camera body to cornea)	45 mm (from objective to cornea)
Working distance detection method	Anterior (Observation) Fundus (Focusing on blight spots)	Anterior (Split Focus) Fundus (Focusing on blight spots)
Minimum diameter of pupil	4 mm	4 mm
CCD Camera for observation	1/3 inch CCD Camera Analog Interlace Scan	1/3 inch CCD Camera Analog Interlace Scan
CCD Camera for Photographing	½ inch CCD Camera Digital Progressive Scan (built-in)	TV Adapter & ½ inch 3 CCD Camera, Analog Non-Interlace Scan (Outer Attachment)
Observation Display (B/W)	6.4 inch LCD Monitor	5 inch CRT Monitor
Photographing Display (Color	6.4 inch LCD Monitor	Outer Monitor (Option) Use
Dioptric compensation	Total –32 D to +40 D	Total -33D to +35D
Focusing	Manual (motor driven) Split line focus on the retina (-10 to +14 D)	Manual Split line focus on the retina (-12 to +15)
Observation Light Source	Halogen lamp (Max. 12V 50W) with infrared filter	Halogen lamp (Max. 12V 75W) with infrared filter
Photographing Light Source	Xenon flash (Max. 25WS)	Xenon flash (Max. 300WS)

PREDICATE DEVICE COMPARISON CHART		
	Nidek Non-mydriatic Fundus Camera Model NM-100	**Canon CR6-45NM K980246**
Internal Fixation Navigation	Manual lever moving	LCD Display
Switching light path of observation & photographing	Beam Splitter	Mobile Mirror
Image File Function	Compact Flash Memory with PC Card adapter	Connection to external device
Data Input	15 characters, by the use of a numeric keypad	Manual writing data (write on the card and slide it in)
Observation Light Adjustment	Volume adjustment style	Volume adjustment style
Photographing Light Adjustment	Step adjustment style (8 steps)	Step adjustment style (5 steps)
CAMERA STAND (BASE):		
Type	Table top; power source built-in	Table top; power source built-in
Horizontal Movement	65 mm forward and backward, 106 mm left and right	40 mm forward and backward 100 mm left and right
Vertical Movement	30 mm	40 mm
Shutter Release	Joystick upper button	Joystick upper button
Signal Outlet	USB, RGB Analog, NTSC Composite Video	RGB Analog, NTSC or PAL Composite Video (depending on CCD camera)
CHINREST:		
Vertical movement of chinrest	65 mm	70 mm
External Fixation Targets	Free-arm style (option)	Free-arm style (option)

7. PERFORMANCE DATA

The following testing was performed on the Nidek Non-Mydriatic Fundus Camera Model NM-1000 to demonstrate that it meets all specified requirements and is equivalent to the predicate device:

A. Electrical Safety Testing & Electromagnetic Compatibility

The Nidek Non-Mydriatic Fundus Camera Model NM-1000 was tested in accordance with EN 60601-1 and EN 60601-1-2, and was found to meet all requirements of both standards.

B. Programmable Electrical Medical Systems

The Nidek Non-Mydriatic Fundus Camera Model NM-1000 was tested in accordance with EN 60601-1-4 and was found to meet all requirements of the standard.

C. Test Requirements and Test Methods for Ophthalmic Instruments

The Nidek Non-Mydriatic Fundus Camera Model NM-1000 was tested in accordance with ISO 15004 and was found to meet all requirements of the standard.

8. CONCLUSIONS

Nidek Incorporated has demonstrated through its evaluation of the Nidek Non-Mydriatic Fundus Camera Model NM-1000 that the device is equivalent to the predicate device with respect to intended use, technological characteristics, and safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nidek Inc.
C/O Mr. Carol Patterson
President
Patterson Consulting Group, Inc.
21911 Erie Lane
Lake Forest, CA 92630

APR 17 2002

Re: K014274
Trade/Device Name: Non-Mydriatic Fundus Camera, Model NM -1000
Regulation Number: 21 CFR 886.1120
Regulation Name: AC-powered ophthalmic camera
Regulatory Class: Class II
Product Code: HKI
Dated: April 9, 2002
Received: April 11, 2002

Dear Ms. Patterson:

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

INDICATIONS FOR USE

510(k) Number: K014274 (To Be Assigned By FDA)

Device Trade Name: Nidek Non-Mydriatic Fundus Camera Model NM-1000

Indications For Use: The Nidek Non-Mydriatic Fundus Camera Model NM-1000 is an ophthalmic camera that is indicated for use in capturing images of the retina and the anterior segment of the eye.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

2-26-02

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

510(k) Number K014274

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)