K991284

510(k) SUMMARY

[As required by 21 CFR 807.93]

I GENERAL INFORMATION

Applicant's Name & Address:	Nidek Incorporated 47651 Westinghouse Drive Fremont, California 94539-7474
Contact:	Mr. Jerry Tsutsumi Regulatory/Quality Manager
Date Summary Prepared:	12 April 1999

II DEVICE NAME

Trade or Proprietary Name:	Anterior Eye-Segment Analysis System
Model Number:	EAS-1000
Common/Classification Name:	Ophthalmic Camera
Class:	Class II
Classification Panel:	86
Product Code:	MXK
Regulation Number:	886.1850

III PREDICATE DEVICES

The Nidek EAS-1000 Anterior Eye-Segment Analysis System is claimed to be substantially equivalent to the following currently Marketed Devices:

- Nidek, 3-DXF Stereo Fundus Camera - **K973533** – received 11/4/ 97
- KOWA Optimed Inc., SC-1200 Slit Lamp – **K955442** – received 1/3/96

IV PRODUCT DESCRIPTION

This DEVICE is a non-invasive, table mounted, AC powered diagnostic sytem intended to take photographs of the eye and surrounding area. The system contains a illumination device, viewing optics, a computer (CPU), image capturing devices, and is based on the Scheimpflug Principle for Slit Image photography. The system uses a Xenon flash lamp for Flash Photography, and an Infrared LED for Retro-Illumination.

	NEW DEVICE	PREDICATE DEVICE	PREDICATE DEVICE
Manufacturer	**Nidek Inc.**	**Nidek Inc.**	Kowa Optimed
Model Name	**EAS-1000**	**3DXF Stereo Fundus Camera**	**KOWA SC-1200**
Optical	**Single Aperature**	Stereo Aperature	**Single** or Stereo **Aperature**
Viewing Optics	**5.5" Black & White CRT**	Eyepiece, Stereo Viewing Optics	Eyepiece, Stereo/Mono Viewing Optics
Observation Illumination	**Infrared LED for Retro-Illumination 800 nm**	Halogen Lamp 50W	Halogen Lamp 30W
Flash Output Illumination	**Xenon Lamp 200Wsec**	**Xenon Lamp 200Wsec**	Xenon Lamp 300W
Exposure Control	**4 Step – Selectable (50, 100, 150, 200 WS)**	5 Step – Manual (25, **50, 100, 200**, 400 WS)	5 Step – Manual (25, **50, 100, 200**, 300 WS)
Photography Camera	**CCD Camera**	35 mm Film Plane or Polaroid Media	35 mm Film Plane or Polaroid Media
Display	**Data digital and can be displayed on a CPU**	Image is a film hard copy only	Image is a film hard copy only
Image resolution	**640 x 400 pixels**	N/A	N/A
Image Size	**8 mm X 6.6 mm**	20 mm X 16 mm (stereo)	24 mm X 17 mm (stereo) 24 mm X 24 mm (mono) 24 mm X 36 mm (right)
Photographic Ranges	**Offers Photographic angles from 0 to 180°**	Offers a swing angle of 15° right or left	Offers a Slit Projection angle of 90° from vertical
Photographic Magnification	**0.5 X**	2.6X	0.7, 1.1, 1.7, 2.8, 4.3X Stereo
Slit Length	**2 ~ 14 mm, adjustable**	N/A	0 ~ 11 mm, adjustable
Power Consumption	**150 VA**	600 VA	1300 VA
Power Requirement	**100 Vac 50/60 Hz**	AC 100, 120, 220, 240V 50/60 Hz	AC 100, 117 , 220, 240V 50/60 Hz
Weight	**25 Kg**	30 kg	N/A

V INDICATIONS FOR USE

Intended Use: The EAS-1000 is intended to take photographs of the eye and surrounding area, which includes the cornea, aqueous, lens, vitreous and retina of the eye. To evaluate:

- corneal shape,
- and analyze conditions of lens (opaque crystalline lens),
- the state of lens (pre and post Intraocular Lens Transplant),
- and analyze anterior chamber angles,
- and analyze anterior or posterior cortical opacity,
- the degree and location of cataracts (nuclear, subcapsular and or cortical) using cross slit imaging or retro-illumination, or both with densitometry and biometry analyses where applicable.

VI CLINICAL PERFORMANCE DATA

Published Journal Articles were supplied to support the claims for use, accuracy, safety and effectiveness of the EAS-1000 for the prescribed intended uses defined in this submission.

VII NON-CLINICAL PERFORMANCE DATA

None provided at this time.

VIII RATIONAL FOR SUBSTANTIAL EQUIVALENCE

The GENERAL INTENDED USES of all three of these devices is "to take photographs of the eye and surrounding area".

Our claim of Substantial Equivalence, and is also based on the following;

- The devices compared, utilize the same or similar OPERATING PRINCIPLES, in that they all contain an optical system, a source of illumination for observation, a source of illumination for photography, and photographic mediums.
- All three devices utilize the same DEVICE FEATURES, a Head Stabilizing device, an External Fixation Target, a Joy Stick or Control Mechanism, and a Exposure Control.
- All three devices utilize a ILLUMINATION SOURCE, and a FLASH OUTPUT SOURCE, and safety concerns regarding "Photo Toxicity" is not an issue with these devices.
- All three devices are considered "Non Invasive" devices as defined in **21 CFR §812.3(k)** and are considered NOT to be a "Significant Risk Device" as defined in **21 CFR §812.3(m).**

IX SAFETY AND EFFECTIVENESS

The EAS-1000 is a non-invasive diagnostic system and only contacts the patient on his/her chin and forehead, and DOES NOT present or pose any new or additional significant effects or risks on the safety, performance, use or effectiveness for its prescribed intended uses. Light safety concerns or "Photo Toxicity" is not an issue with this device as light output is of an eyesafe intensity and wavelength. Electrical Safety requirements for medical device are met. The device is proven effective for its intended uses through internal company and independent international clinical studies. The information provided in this submission reasonably assures this product to be Safe and Effective for it intended uses.

X CONCLUSION

We believe that the data submitted in this document, demonstrates that the EAS-1000 is substantially equivalent with respect to the indications for use, operating principles, and the device features to other legally market predicate devices. The safety and effectiveness of this product can be reasonably assured, as the EAS-1000 DOES NOT pose any new or additional significant effects on the safety, performance, use or effectiveness of this device for its prescribed intended uses. We believe that this device clearly meets the requirement for substantial equivalence according to the 510(k) guidelines. Therefore, justifying 510(k) PreMarket Notification Clearance for commercial sale and distribution of this product within the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG -6 1999

Mr. Jerry Tsutsumi
Regulatory/Quality Manager
Nidek Incorporated
47651 Westinghouse Drive
Fremont, California 94539-7474

Re: K991284
Trade Name: Anterior Eye-Segment Analysis System
Regulatory Class: II
Product Code: 86 MXK
Dated: July 13, 1999
Received: July 14, 1999

Dear Mr. Tsutsumi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Concurrence of CDRH ODE Form

510(k) Number (if known): K991284

Device Name: Nidek Inc. EAS-1000 Anterior Eye Segment Analysis System

INDICATIONS FOR USE:

The EAS-1000 "Anterior Eye-Segment Analysis System" is intended to take photographs of the eye and surrounding area, for non-invasive illumination, magnification, observation, analysis and photography of the anterior segments of the eye, which include the cornea, aqueous, lens, vitreous and retina of the eye. To evaluate and analyze conditions of lens (opaque crystalline lens), lens position (pre and post Intraocular Lens Transplant), anterior or posterior cortical opacity, cataracts (nuclear, subcapsular and or cortical) using cross slit imaging or retro-illumination, or both with densitometry and biometry analyses where applicable.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K991284

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)