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SECTION 14: SUMMARY OF SAFETY AND EFFECTIVENESS

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

14.1 SUBMITTER INFORMATION

a. Company Name:	Nidek, Inc.
b. Company Address:	47651 Westinghouse Drive Fremont, CA 94539
c. Company Phone: Company Facsimile:	(510) 226-5700 (510) 226-5750
d. Contact Person:	Hiro Matsuzaki Quality Assurance Manager
e. Date Summary Prepared:	February 4, 2002

14.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	DC-3300 Laser Diode Photocoagulation
b. Classification Name:	Ophthalmic Laser 21 CFR 886.4390 HQF

14.3 IDENTIFICATION OF PREDICATE DEVICES

Company	Device	510(k) No.	Date Cleared
Nidek, Inc.	DC-3000 Laser Diode Photocoagulator	K903639	02/04/1991
Iriderm	Iris OcuLight SLx	K913430	11/15/1991
Iriderm	Iris OcuLight Diode Laser With Slit Lamp Adapter	K912918	08/23/1991

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14.4 DEVICE DESCRIPTION

The DC-3300 Laser Diode Photocoagulator is an 808 nm continuous wave device. The DC-3300 consists of a compact, lightweight main console, footswitch and carrying case. The aiming laser of the DC-3300 is a red diode with a wavelength of 633 nm. A number of delivery systems are available with the DC-3300. A Slit Lamp Delivery Unit (Nidek SL-1600) Multipurpose Delivery Unit for the attachment of slit lamps (Nidek SL-1600), Endophotocoagulation Set, Binocular Indirect Ophthalmoscope (Models A and B), and Transscleral Photocoagulation probes.

14.5 SUBSTANTIAL EQUIVALENCE

The DC-3300 Laser Diode Photocoagulator is substantially equivalent to the Nidek DC-3000 Laser Diode Photocoagulator and the Iriderm Iris OcuLight SLx.

The fundamental technical characteristics and device specifications of the DC-3300 Laser Diode Photocoagulator are the same as those of the predicate devices. The DC-3300 and the predicate devices are diode photocoagulation lasers with a wavelength of 810 nm. The DC-3300 and the OcuLight SLx use a variety of delivery systems, including slit lamps, indirect ophthalmoscopes, endoprobes, and transscleral probes. The DC-3300 and the OcuLight SLx are indicated for all retinal photocoagulation and glaucoma procedures.

14.6 INDICATIONS FOR USE

The Nidek DC-3300 Laser Diode Photocoagulator is indicated for all retinal photocoagulation procedures, such as limited and pan-retinal, transpupillary laser photocoagulation, endophotocoagulation and transscleral photocoagulation, and glaucoma procedures, such as laser trabeculoplasty and iridotomy. The DC-3300 is used in combination with various delivery systems, such as slit lamps, binocular indirect ophthalmoscopes, endoprobes and transscleral probes.

14.7 TECHNOLOGICAL CHARACTERISTICS

The DC-3300 Laser Diode Photocoagulator is a continuous wave 808 nm laser for ophthalmic photocoagulation procedures. The compact design of the system makes it portable and easily relocated. The aiming laser of the DC-3300 is a red diode with a wavelength of 633 nm. The delivery systems include the Slit Lamp for the attachment of the Nidek SL-1600, the Multipurpose for the attachment of the Nidek SL-1600 slit lamp, Endoprobes (two angled and two straight configurations), Transscleral probes (contact, non-contact and retinal), and two models of the Binocular Indirect Ophthalomoscope (Keeler All-Pupil and Heine Omega 180). The technological characteristics of the DC-3300 are equivalent to those of the predicate devices.

14.8 PERFORMANCE DATA

Performance testing was conducted on the DC-3300 Laser Diode Photocoagulator and delivery systems. System and component testing was completed based on product specifications and hazard effects determined from the risk analysis. The device was found to be in conformance with the following international safety standards: IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-22, IEC 60825-1, and UL 2601-1. The DC-3300 was found to perform as intended.

14.9 CONCLUSION

This notification contains all information required by 21 CFR 807.87. The DC-3300 Laser Diode Photocoagulator was found to perform as intended during validation testing. The DC-3300 is substantially equivalent to the Nidek DC-3000 and Iriderm Iris OcuLight SLx devices. Product specifications and technical characteristics are within the same range of specifications for the predicate devices. The evaluation of the product specifications, performance testing and risk analysis does not raise any new issues of safety or effectiveness. The DC-3300 is intended for all retinal photocoagulation and glaucoma procedures and is combined with various delivery systems to perform its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2002

Nidek, Inc.
Ms. Carol Patterson
c/o Patterson Consulting Group, Inc.
21911 Erie Lane
Lake Forest, California 92630

Re: K013760
Trade Name: Nidek C-3300 Laser Diode Photocoagulation
Regulation Number: 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: II
Product Code: HQF; GEX
Dated: November 9, 2001
Received: November 13, 2001

Dear Ms. Patterson:

We have reviewed your Section 510(k) premarket 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) 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) 594-4659. 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,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number: K013760

Device Name: Nidek DC-3300 Laser Diode Photocoagulator

Indications for Use: The Nidek DC-3300 Laser Diode Photocoagulator is indicated for all retinal photocoagulation procedures, such as limited and pan-retinal, transpupillary laser photocoagulation, endophotocoagulation and transscleral photocoagulation, and glaucoma procedures, such as laser trabeculoplasty and iridotomy. The DC-3300 is used in combination with various delivery systems, such as slit lamps, binocular indirect ophthalmoscopes, endoprobes, and transscleral probes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013760

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)