



NIDEK
Incorporated

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MAY 13 1998

510(k) SUMMARY

K980547

This is a 510(k) Summary in accordance with CFR 807.92.

1. Submitter:

Nidek Inc. for
Nidek Co., Ltd.,
34-14 Maehama Hiroishicho
Gamagori, 443

Correspondent:

Ken Kato, VP
Phone: (510)226-5700
Fax: (510)226-5750

2. Device Name:

Models GYC-1500 and GYC-2000
Solid state ophthalmic laser photocoagulator
Ophthalmic Laser

3. Predicate Devices:

Model Ophthalas 532 by Alcon (K962592)
Model Cerlas G by CeramOptec (K962948)
Model Oculight GL by Iris (K960971)
Models GYC-1500/2000 (K951079) - The purpose of this application is to add two indications of: iridotomy and trabeculoplasty, to the current 510(k). GYC-1500 has max. power of 1.5W and 2000 of 2.0W.

4. Intended Use:

The Nidek Frequency Doubled Nd:YAG Laser is intended to be used in all clinical applications for which an Argon Laser would be used in ophthalmic surgery, including but not limited to Retinal and Macular Photocoagulation; Iridotomy

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FDA/CDRH/ODE/DMC

and Trabeculoplasty.

5. Device Description:

The Nidek GYC-1500/2000 Solid State Photocoagulators are frequency doubled Nd:YAG lasers producing a characteristic 532 nanometer (nm) wavelength light as treatment beam. A 633nm helium-neon (HeNe) laser is used for the aiming beam source.

The doubling process of the 1064nm wavelength results when the infrared beam goes through a special crystal, which is an optical dielectric that exhibits a non-linear optical response. The 532nm - Green - wavelength is produced by harmonic generation of the 1064nm laser beam.

The laser treatment beam is delivered through the cornea to the target tissue by an optical delivery system which is mounted either on a slit lamp microscope or binocular indirect microscope. Tissue may also be treated inter-operatively by direct radiation from a fiber optic end-ocular probe or a optical deliver system mounted on an operating microscope. The beam may be further manipulated by accessory contact lenses or near contact "aspheric" lenses. An aiming beam is provided by the system to indicate the target tissue prior to the treatment exposure.

The desired treatment parameters of power exposure duration, and spot size are selected as required. The location and operation of all controls and indicators is described in the Nidek Prima Frequency Doubled Nd:YAG Operator Manual. Treatments are always started with the lowest applicable exposure and the dosage is increased until the desired effect is obtained.

6. Significant Changes/Modifications from Predicate Device:

There are no significant changes or modifications from the predicate products that affects safety, effectiveness, or the intended use of the product.

7. Device Labels:

Copies of advertising brochure, operator's manual with product label information are attached.

8. Comparative Information:

Comparison table is attached to show the similarities and differences of the GYC

to the predicate devices.

9. Software Validation & Verification:

As the part of its quality system controls, Nidek has implemented the software development process which is described and defined in the Software Development Procedure. Changes on software are made in accordance with the Design Change Standard Procedure. These procedures address the requirements for software specification, design change control, and design verification and validation. At each phase, design reviews are conducted to ensure that policies and procedures are being followed and that requirements are being met.

During the development phase, overall design requirements (specifications) and software specification are developed. Based on the system requirements and software specifications, a hazard (risk) analysis is conducted and, where necessary, methods of mitigation defined. At the design review, reviewers verify that specification effectively address design requirements.

During the coding phase, the software specifications are translated, with the aid of appropriate software tools, into source, object and executable code. At the design review, reviewers, using procedures such as code walk through, verify that code address elements defined in the specifications.

During the module and integration testing phase, software emulation and prototyping tools are utilized to test module and larger sections of code. After module testing, the software is integrated with the target system and validation testing conducted. This testing ensures that specifications and system requirements have been met.

During the approval/release review, Engineering and Quality Assurance management verifies that required documentation is present and approved. The verification and validation reports are reviewed to assure that system specifications and requirements have been met.

These established policies and procedures ensure that current and future software development projects, including changes, will be verified and validated against appropriate software and system requirements and specifications.

Signed: Ken Kato
Ken Kato, VP

Date: FEB 11 1998



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 1998

Mr. Ken Kato
Vice President
Nidek Incorporated
47651 Westinghouse Drive
Fremont, California 94539

Re: K980547
Trade Name: Nidek Prima Model GYC-1500/2000 Solid State
Photocoagulator
Regulatory Class: II
Product Code: GEX
Dated: February 11, 1998
Received: February 12, 1998

Dear Mr. Kato:

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.

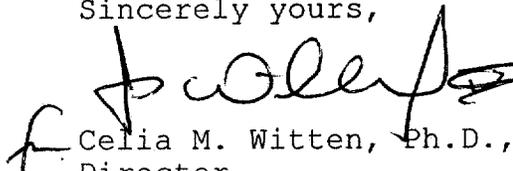
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, 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.

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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) 594-4595. 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,



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

Enclosure

510(k) Number (if known): K980547

Device Name: GYC-1500/2000

Indications For Use:

The Nidek Prima Frequency doubled Nd:YAG Laser is intended to be used in all clinical applications for which an Argon Laser would be used in ophthalmic surgery, including Retinal and Macular Photocoagulation; Iridotomy and Trabeculoplasty.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980547

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____