**SECTION 6**
**510(k) SUMMARY (CONT.)**

**510(k) Notification K** K110228

FEB 2 3 2011

**GENERAL INFORMATION**

**Applicant:**
Nidek Incorporated
47651 Westinghouse Drive
Fremont, CA 94539-7474
U.S.A.
Phone: 510-226-5700
Fax: 510-226-5750

**Contact Person:**
Kit Cariquitan
Vice President, Regulatory Affairs
Experien Group, LLC
155-A Moffett Park Drive, Suite 210
Sunnyvale, CA 94089-1330
U.S.A.
Phone: 408-400-0856 ext. 112
Fax: 408-400-0865
Email: kitc@experiengroup.com

**Date Prepared:** January 24, 2011

**Classification:**
21 CFR§878.4810 and §886.4390, Class II

**Product Code:**
GEX, HQF

**Trade Name:**
Nidek Multicolor Laser Photocoagulator System MC-500

**Generic/Common Name:**
Ophthalmic Laser Photocoagulator

**Predicate Device**
Nidek Multi Color Laser Photocoagulator Model MC-300 (K042785)

**Intended Use**
The Nidek Multicolor Laser Photocoagulator System MC-500 is intended to be used in ophthalmic surgical procedures, including retinal and macular photocoagulation, iridotomy and trabeculoplasty.

## SECTION 6
## 510(k) SUMMARY (CONT.)

### Product Description

The Nidek Multicolor Laser Photocoagulator System MC-500 ("MC-500") is a conventional ophthalmic laser photocoagulator system with treatment light wavelengths of 532 nm, 577 nm, and 647 nm. The system is comprised of a diode aim and treatment lasers, graphical user interface, slit lamp and binocular indirect ophthalmoscope delivery units, and a footswitch.

### Substantial Equivalence

The MC-500 is substantially equivalent to the predicate device with regard to design, function, technological characteristics, intended use and performance characteristics. Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Thus, the proposed MC-500 is substantially equivalent to the predicate device.

### Testing in Support of Substantial Equivalence Determination

All necessary bench testing was conducted on the proposed MC-500 to support a determination of substantial equivalence to the predicate device.

### Summary

The MC-500 is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Nidek Incorporated
% Experien Group, LLC
Kit Cariquitan
155-A Moffett Park Drive, Suite 210
Sunnyale, California 94089

FEB 2 3 2011

Re: K110228
Trade/Device Name: Nidek Multicolor Laser Photocoagulator System MC-500
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: II
Product Code: HQF
Dated: January 24, 2011
Received: January 26, 2010

Dear Kit Cariquitan:

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**SECTION 5**
**INDICATIONS FOR USE STATEMENT**

510(k) Number (if known): K110228

Device Name: Nidek Multicolor Laser Photocoagulator System MC-500

**Indications for Use:**

The Nidek Multicolor Laser Photocoagulator System MC-500 is intended to be used in ophthalmic surgical procedures, including retinal and macular photocoagulation, iridotomy and trabeculoplasty.

Prescription Use _X_ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110228