DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 12, 2014

NIDEK Company, LTD
% Mr. Enrico Bisson
Nidek Technologies srl
Via dell'Artigianato, 6/A
35020 Albignasego (Padova), Italy

Re: K133358
Trade/Device Name: Endophotocoagulation Delivery Unit
(for sterilized endophoto probe)
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX, HQF
Dated: July 9, 2014
Received: July 21, 2014

Dear Mr. Bisson:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K133358

Device Name
Endophotocoagulation Delivery Unit (for sterilized endophoto probe)

Indications for Use *(Describe)*
The Endophotocoagulation Delivery Unit (for sterilized endophoto probe) is intended to be used in ophthalmic surgical procedures for retinal photocoagulation. Spot size can be varied by altering the distance between the tissue and the probe tip.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

# 510(K) SUMMARY

This summary of the 510(k) premarket notification for the Endophotocoagulation Delivery Unit (for sterilized endophoto probe) is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

510(k) Notification **K133358**

GENERAL INFORMATION

**Applicant:**

NIDEK CO., LTD.
34-14 Maehama, Hiroishi
Gamagori, Aichi, 443-0038 Japan

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|---|---|
| Contact Person: | Yoneji Mizuno |
| Contact Title: | Senior Manager, Regulatory Affairs Department |
| Contact Phone Number: | +81-533-67-8901 |
| Contact Fax Number: | +81-533-67-6628 |
| E-mail: | Yoneji_Mizuno@nidek.co.jp. |

| | |
|---|---|
| **Official Correspondent:** | Enrico Bisson |
| Contact Title: | Manager, Regulatory Affairs Department<br>Nidek Technologies Srl<br>Via dell'Artigianato, 6/A,<br>35020 Albignasego (Padova) , Italy |
| Contact Phone Number: | +39-049 8629200 |
| Contact Fax Number: | +39-049 8626824 |
| E-mail: | enricobisson@nidektechncologies.it |

**Date Prepared**: August 7, 2014

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

**Classification name:**
Laser surgical instrument for use in general and plastic surgery and in dermatology

**Product Code:**
GEX, HQF

**Trade Name:**
Endophotocoagulation Delivery Unit (for sterilized endophoto probe)

**Generic/Common Name:**
Endophotocoagulation Delivery Unit (for sterilized endophoto probe)

**Predicate Device**
Multicolor Laser Photocoagulator System MC-500 (K110228)
OphthalMed 20G and 25G SMA Laser Fibers (K021696)
Peregrine 23ga Curved Illuminating Laser Probe (K122997)
Green Laser Photocoagulator GYC-1000 (K032085)

**Indications for use**
The Endophotocoagulation Delivery Unit (for sterilized endophoto probe) is intended to be used in ophthalmic surgical procedures for retinal photocoagulation. Spot size can be varied by altering the distance between the tissue and the probe tip.

**Product Description**
The Endophotocoagulation Delivery Unit (for sterilized endophoto probe) is connectable to Nidek laser photocoagulators such as NIDEK Multicolor Laser Photocoagulator System MC-500 or Green Laser Photocoagulator Model GYC-1000 and to the additional following surgical microscopes:.

| Surgical microscope manufacturer | Surgical microscope model |
|---|---|
| CARL ZEISS MEDITEC | OPMI VISU 140 |
| | OPMI Lumera i |
| | OPMI Lumera T |
| TOPCON | OMS-800 |
| | OMS-710 |
| | OMS-90 |
| TAKAGI SEIKO | OM-18 |
| LEICA MICROSYSTEMS (formerly WILD) | M844/M820 |
| | M620 |

The delivery unit, which consists of a sterilized endophoto probe (available in 3 different sizes and 2 different shapes), protective filter unit, and carrying case, is used for endophotocoagulation.

The photocoagulation system can be easily assembled by connecting the sterilized endophoto probe to the main laser device and connecting the protective filter to the laser device and surgical microscope.

This photocoagulation system enables laser endophotocoagulation while observing the affected area through the surgical microscope.

**Substantial Equivalence**

The Endophotocoagulation Delivery Unit (for sterilized endophoto probe) is substantially equivalent to the predicate devices with regard to design, function, technological characteristics, intended use and performance characteristics.

The differences between the proposed and predicate devices and justifications as to why these differences do not raise safety or efficacy concerns are as follows:

- The maximum laser output and the wavelength of the proposed device is different from those of the predicate devices.
- The total length of the endophoto probes of the proposed device is different from that of the predicate devices.
- The fixed protective filter is not covered by the predicate devices.
- The cable length of the protective filters of the proposed device is different from that of the predicate devices.

The design modifications outlined in this Traditional 510(k) premarket notification do not (1) affect the intended use or the indication for use or (2) alter the fundamental scientific technology of the device. The proposed Endophotocoagulation Delivery Unit shares the substantially equivalent indications for use, the substantially equivalent technological characteristics and substantially equivalent principle of operation as the predicate devices. Therefore, based on the similarities between the devices, the proposed Endophotocoagulation Delivery Unit is substantially equivalent to

- OphthalMed 20G and 25G SMA Laser Fibers (K021696)
- SL-1800 attachable delivery unit Multicolor Laser Photocoagulator System MC-500 (K110228)
- Peregrine Surgical 23ga Curved Illuminating Laser Probe (K122997), a probe with a similar irradiance

- Green Laser Photocoagulator GYC-1000 (K032085)

**Testing in Support of Substantial Equivalence Determination**
We have verified and validated that the Endophotocoagulation Delivery Unit (for sterilized endophoto probe) meets its functional specifications and performance requirements, and complies with applicable international standards (ISO10993-1).

As mentioned, all necessary bench testing was conducted on the modifications, the addition of the proposed Endophotocoagulation Delivery Unit (for sterilized endophoto probe), to support a determination of substantial equivalence to the predicate devices.

**Non clinical sterility testing**
The sterilization re-validation protocol was provided and the EO and ECH residual testing of the subject devices following the procedures, methods, and limits for a simulated extraction (since the product is categorized as a limited exposure device), described in the FDA-recognized standard, ANSI/AAMI/ISO 10993-7:2008 (R2012) "Biological evaluation of medical devices— Part 7: Ethylene oxide sterilization residuals" was conducted. This testing demonstrated that EO and ECH residue levels after sterilization of the endophoto probe are below the current limits for intraocular lenses, it means not exceed 1.25 micrograms and 5 micrograms (respectively), testing just the endophoto probe tip.

Regarding expiration date, the sterilized endophoto probes have a shelf life of 3 years. As the basis for setting the shelf life, the seal integrity and product sterility were tested at 3 accelerated or real years and finally concluded that the shelf life of 3 years is claimed.

**Non clinical safety testing**
Both the electrical safety test report according to IEC 60601-1 and the Electromagnetic Compatibility test report according IEC 60601-1-2 were provided. The mechanical properties of all the endophoto probes were tested according to ISO 9626 and the results confirmed the ability of the device to withstand the forces it will be subjected during normal use.

**Summary of Safety and Effectiveness**
The results demonstrate that the subject device complies with applicable international standards (ISO10993-1). All the necessary non clinical performance tests in support of substantial equivalence determination were conducted.

Thus the proposed Endophotocoagulation Delivery Unit (for sterilized endophoto probe) is substantially equivalent to the predicate devices.