MAR 18 1998

NIDEK
Incorporated

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K974732

## 510(k) SUMMARY

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 Japan

   Correspondent:

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

2. Device Name
   Nidek MC-7000
   Photo coagulator

3. Predicate Devices
   Coherent Novus Omni made by Coherent (K932468)
   HGM Spectrum K5 made by HGM (K930543)

4. Intended Use
   Laser beam generated by MC-7000 is to be used for photocoagulation in ophthalmic indications in transpupillary and inter operative areas as in:

   | | |
   |---|---|
   | Transpupillary | Retinal Photocoagulation, either limited or Pan-Retinal |

| | |
|---|---|
| | Macular Photocaogulation |
| | Trabeculoplasty for Open Angle Glaucoma |
| | Iridotomy for Acute Angle Closure Glaucoma |
| Inter Operative | Retinal Photocoagulation, either limited or Pan-Retinal |
| | Macular Photocoagulation |

5. Device Description

The Nidek MC-7000 now combines the benefits of Red, Yellow, Yellow-Green, and Green wavelengths into one single laser photocoagulation system. It's designed to work with the variety of slit lamp delivery systems in ophthalmology, and performs extended applications in endo and laser indirect photocoagulation.

The MC-7000's design provides reliablility and ease of use. Its self-contained cooling eliminates the need for external cooling fixtures. The display panel attaches to the front of the console, or detaches to function as a remote, either way providing clear, concise information on settings and energies during every procedure.

| | |
|---|---|
| Laser Source | Multi-wavelength Single Tube Krypton Laser |
| Wavelength | Red: 647.1nm |
| | Yellow: 568.2nm |
| | Green: 520.8 - 530.9nm |
| Power To Cornea | Red: 50 - 1000mw |
| | Yellow: 50 - 600mw |
| | Yellow/Green: 50 - 1500mw |
| | Green: 50 - 900mw |
| Exposure Times | .02 sec to continuous (21 steps) |
| Auto - Repeat | .2 - 1.0 sec between exposures (9 steps) |
| Aiming Beam | 670nm Diode red, .8mw or less to the cornea. |
| Deliver Systems | Nidek SL1600, Zeiss SL130 Full System, 30SL Adaptor, Haag 900BQ Full System, BIO, MIO, Combo, Endoprobe, OM adaptor |
| Spot Sizes | Nidek SL1600 (50 - 1000mic.m Parfocal, 1000 - 2000mic.m Defocused) |
| | Zeiss SL130 (50 - 1000mic.m Parfocal, 1000 - 2000mic.m |

| | |
|---|---|
| | Defocused) |
| | Haag 900BQ (50 - 990mic.m Parfocal) |
| | Slit Lamp Adaptor (50 - 500mic.mParfocal) |
| Light Cable | 50mic.m Fiber, 2.5m |
| Cooling | Internal Water Cooling |
| Power Requirements | 190 -245V AC, 3 Phase, 50 Amp |
| Size | Console - 16 x 39 x 48 |
| Weight | 389lbs |

6. Significant Changes/Modifications from Predicate Device

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

7. Device Labels

   Draft copies of advertising brochure and operator's manual are attached. Products labels information is included in the manual.

8. Comparative Informatio

   Comparison table is attached to show the similarities and differences of the MC-7000 to the predicate device.

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, VP

Date: Dec. 12 '97

97/10/20

# MULTI-COLOR LASER PHOTOCOAGULATOR comparison table

| | | | NIDEK MC-7000 | Coherent NOVUS OMNI | HGM SPECTRUM K5 |
|---|---|---|---|---|---|
| 1 | POWER (mW) | Green (520.8、530.9 nm) | 50～900 | 50～900 | ～1900 |
| | | Yellow (568.2 nm) | 50～600 | 75～600 | ～900 |
| | | Yellow・Green | 50～1500 | 75～1500 | |
| | | Red (647.1 nm) | 50～1000 | 50～1000 | ～1650 |
| 2 | EXPOSURE TIME (sec) | | 0.02～CW (21 step) | 0.01～CW | 0.03～5 (8 step) |
| 3 | REPEAT MODE | | standard function | same | same |
| | INTERVAL TIME (sec) | | 0.2～1.0 (9 step) | up to 9.1 Hz | 10.0～0.2 Hz (7 step |
| 4 | DELIVARY SYSTEM | SLITLAMP | Zeiss SL130 full system | same | NA |
| | | | ※1 Zeiss 30SL adapter | Laser Link Z | Zeiss 30SL full system |
| | | | ※2 Haag Streit 900BQ full system | NA | NA |
| | | | ? (Nidek SL-450、SL-1600) | NA (Coherent Model) | NA (HGM Model) |
| | | | ※3 YC-COMBO (YC-1300、1400) | NA | NA |
| | | others | ※3 BIO (Heine or Keeler) | BIO Keeler only | ? |
| | | | ※3 MIO Neitz (Japan) | NA | NA |
| | | | ※3 Operation Microscope Adapter | NA | NA |
| | | | ※3 Endophotocoagulation Probe Straight、Angled、Illum. Combined | same Straight、Angled only | ? |
| 5 | SPOT SIZE (μm) | | 50～2000 (SL130)<br>50～990 (900BQ)<br>Parfocal (below 1000) | 50～500 (SL130、Laser Link)<br>Sure-Spot (defocus?) | 50～1000<br>Parfocal |
| 6 | AIMING | | LD (670 nm) | same | ? |

| | | NIDEK MC-7000 | Coherent NOVUS OMNI | HGM SPECTRUM K5 |
|---|---|---|---|---|
| 7 | LASER POWER CONTROL | Light? On Demand(Low Cur. STDBY) | Power On Demand (No Cur. STDBY | ? |
| 8 | COOLING | Internal Water Cooling | same | same |
| 9 | ELECTRICAL REQUIREMENT | 190~245Vac、16KVA、three phase<br>(190~245Vac、15KVA(75A)、single) | 200~240Vac、35A、three phase<br>200~240Vac、60A、single phase<br>380~415Vac、20A、three phase | 200Vac、13KVA(65A)、single |
| 10 | CONSOLE<br>dimension (W×D×H mm)<br>required floor space ( $m^2$)<br>weight ( kg ) | 411×1002×1230<br>0.41<br>(177) | 460×965×1170<br>0.44<br>159 | 490×870×800<br>0.43<br>135 |
| 11 | FEATURE | ○ Compact<br>○ Easy to Operate<br>○ Dual Delivery (Option)<br>○ Various Delivery Systems | ○ Pioneer System<br>○ Dual Protective Filter (Option)<br>○ Dual Delivery (Option) | ○ High Power<br>○ Two Kr Tubes |
| 12 | PRICE | ¥ 18,500,000 (List Price in Japan) | $ 75,000<br>¥ 19,000,000 (List Price in Japan) | $ 53,000 |

※1 will be developed as 2nd standard delivery system, ※2 as 1st optional delivery and ※3 as 2nd optional delivery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 18 1998

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

Re: K974732
Trade Name: Nidek Multi Color Laser Photocoagulator, Model MC-7000
Regulatory Class: II
Product Code: GEX
Dated: December 18, 1997
Received: December 18, 1997

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 (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 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.

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,

for 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): K974732

Device Name: Nidek MC-7000 Photocoagulator

Indications For Use:

As per attached sheet.

(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 General Restorative Devices
510(k) Number K974732

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

## Indications for Use:

Delivery of Laser therapeutic radiation is accomplished by two basic means:

**Transpupillary:**

1) Via an optical system attached to a viewing microscope either a slit-lamp or operating microscope.

   Retinal therapy is further aided by the use of an auxiliary viewing lenses, typically a fundus laser lens, or a wide field examination lens with a laser anti-reflection coating.

   Anterior segment therapy is further aided by viewing lenses which can reflect the treatment beam into the chamber angle, either with or without magnification. The lens is treated on the distal surface with a laser anti-reflection coating.

2) Via an optical system attached to an indirect ophthalmoscope either binocular or monocular, with or without auxiliary viewing lenses. Typically a +20 Diopter examination lens with a laser anti-reflection coating is employed.

**Inter Operative methods:**

1) Via direct radiation administered from a fiber optic cable handpiece which is inserted through an incision and positioned proximal to a point of treatment within the eye. According to the area to be treated, the fiber handpiece be formed in either a straight or curved manner.

**Transpupillary laser therapy is commonly employed for the following indications:**

Retinal Photocoagulation, either limited or Pan-Retinal
Macular Photocoagulation
Trabeculoplasty for Open Angle Glaucoma
Iridotomy for Acute Angle Closure Glaucoma

**Inter-Operative laser therapy is employed for the following indications:**

Retinal Photocoagulation, either limited or Pan-Retinal
Macular Photocoagulation

Stephen Rhodes

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974732