

K072259

MAY - 6 2008

## Pre-Market Notification 510(k) Summary

### 1. Sponsor Information:

Company Name & Address: NIDEK Company, Ltd.  
34-14 Maehama, Hiroishicho  
Gamagori, Aichi, 443-0038 Japan

Contact Person: Yoneji Mizuno  
Contact Title: Manager Regulatory Affairs  
Contact Phone Number: +81-533-67-8901  
Contact Fax Number: +81-533-67-6610

Date of Summary: May 5, 2008

### 2. Device Name and Classification:

Common and Usual Name: Ophthalmoscope

Proprietary Name: Ophthalmoscope F-10

Classification Name: Ophthalmoscope, AC-Powered  
(21 CFR § 886.1570)

Product Code: MYC

Class: II

Performance Standards: No applicable performance standards have been issued under section 514 or under section 513(b) of the Food, Drug and Cosmetic Act.

Performance Standards issued for Light Emitting Products: 21CFR Part 1040, Section 1040.10 and 1040.11 (Laser Products).

### 3. Predicate Device(s):

K971671: Heidelberg Engineering  
Heidelberg Retina Angiograph FA/ICGA (HRA/C)  
K871268: G. Rodenstock Instrumente, GMBH  
Rodenstock Scanning Laser

**4. Description of Device:**

The Ophthalmoscope F-10 is categorized as a Class 1 confocal laser scanning ophthalmoscope. The F-10 captures and records confocal images of the fundus by laser scanning using a selection of laser colors: IR (infrared), blue, green, and red and affords Indocyanine green (ICG) and fluorescein (FAG) angiography.

**5. Indications for Use:**

The Ophthalmoscope F-10 is intended for use in capturing images of the fundus which can be used for diagnosis of fundus diseases.

**6. Comparison with Predicate Device(s):**

The Ophthalmoscope F-10 is substantially equivalent to the predicate devices identified and other commercially available SLO products. It is similar in characteristics, materials, features, has similar technological features, intended use and indications for use as the predicates, and do not raise any new questions of safety and effectiveness.

**7. Non-Clinical Performance Summary:**

Nidek Company Ltd. has verified and validated that the Ophthalmoscope F-10 meets its functional specifications, performance requirements and complies with applicable U.S. and international standards (IEC 60601-1, 60601-1-1, 60601-1-2, 60825-1 and ISO 15004-2:2007) for products of its kind. This device complies with 21 CFR Parts 1010 and 1040, with the exception of those allowable performance deviations noted in FDA's Laser Notice 50.

**8. Conclusions:**

In summary, Nidek Company Ltd., is of the opinion that the Ophthalmoscope F-10 does not introduce any new potential safety risks, is as effective, and performs as well as devices currently on the market, and concludes that the Ophthalmoscope F-10 is substantially equivalent to the predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAY - 6 2008**

NIDEK Co., Ltd.  
c/o Mr. Paul Sumner  
Vice President of Regulatory, Clinical & Quality Systems  
Arkin Consulting Group, LLC  
1733 Canton Lane  
Marietta, GA 30062

Re: K072259

Trade/Device Name: Ophthalmoscope F-10  
Regulation Number: 21 CFR 886.1570  
Regulation Name: Ophthalmoscope  
Regulatory Class: Class II  
Product Code: MYC  
Dated: April 16, 2008  
Received: April 18, 2008

Dear Mr. Sumner:

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.

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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Malvina B. Eydelman, M.D.  
Director  
Division of Ophthalmic and Ear, Nose  
and Throat Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**4 Indications for Use Statement**

**Indications for Use Statement**

510(k) Number (if known): K072259

Device Name: OPHTHALMOSCOPE F-10

Indications For Use: The Ophthalmoscope F-10 is intended for use in capturing images of the fundus, which can be used for the diagnosis of fundus diseases.

Prescription Use XX AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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*D. [Signature]* 4/24/2008  
(Division Sign-Off)  
Division of Ophthalmic Ear,  
Nose and Throat Devices

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