K132323

**NIDEK CO., LTD.**
34-14, Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, Japan
Manufacturers, Exporters & Importers of Ophthalmic Instruments, and Opto-Electronics Instruments

TEL +81-533-67-6611
FAX +81-533-67-6610
URL http://www.nidek.co.jp
http://www.nidek.com

# 9. 510(K) SUMMARY

FEB 19 2014

Date Prepared October 31, 2013

## SPONSOR/TRADITIONAL 510(K) OWNER/ MANUFACTURER

Nidek Co., Ltd.
34-14 Maehama, Hiroishi-cho, Gamagori,
Aichi, 443-0038 Japan
Telephone: +81-533-67-8901
Facsimile: +81-533-67-6628
Email: yoneji_mizuno@nidek.co.jp
Establishment Registration Number: 8030392

## OFFICIAL CONTACT PERSON

Lena Sattler
Orasi Consulting, LLC.
2856 Whispering Shores Dr.
Vermilion, OH 44089
Telephone: (440) 554-3706
Facsimile: (866) 904-4315
E-mail: lena@orasiconsulting.com

## COMMON/USUAL NAME

Optical Coherence Tomography

## PROPRIETARY OR TRADE NAMES

RS-3000 Advance

**NIDEK CO., LTD.**
34-14, Maehama, Hiraishi-cho, Gamagori, Aichi 443-0038, Japan
Manufacturers, Exporters & Importers of Ophthalmic Instruments, and Opto-Electronics Instruments

TEL +81-533-67-6611
FAX +81-533-67-6610
URL http://www.nidek.co.jp
http://www.nidek.com

## CLASSIFICATION INFORMATION

| | |
|---|---|
| Classification Name: | Ophthalmoscope, A-C Powered |
| Medical Specialty: | Ophthalmic |
| Device Class: | II |
| Classification Panel: | Ophthalmic Device Panel |
| Product Codes: | OBO |

## PRODUCT CODE: CLASSIFICATION / CFR TITLE

| | |
|---|---|
| OBO: | Class II § 21 CFR 886.1570 |

## LEGALLY MARKETED PREDICATE DEVICE

| | |
|---|---|
| Trade/Device Name: | RS-3000 |
| Applicant: | Nidek |
| 510(k) Premarket Notification number: | K121622 |
| Classification: | Class II |
| FDA Product Code: | OBO |
| Establishment Registration number: | 8030392 |

## GENERAL DEVICE DESCRIPTION

The NIDEK Optical Coherence Tomography RS-3000 Advance is an ophthalmic camera that allows non-invasive and non-contact observation of the fundus and its ocular structures. The device captures an image of the fundus using both a Scanning Laser Ophthalmoscope and Optical Coherence Tomography.

The Nidek RS-3000 Advance is a non-contact ophthalmic imaging system for the viewing and axial cross sectional imaging of ocular structures. It is used for in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as an aid in the diagnosis and management of the retinal disease. In addition, the anterior segment adapter (special lens unit) attached over the objective lens of the main body enables non-invasive and non-contact observation of the shape of the anterior segment of the eye such as the cornea or anterior chamber angle.

Fundus images (hereafter referred to as SLO image) are captured with the confocal laser scanning using a near-infrared light source with a wavelength of 785 nm. Cross-sectional images of the fundus (hereafter referred to as OCT image) are captured with the optical interferometer using an infrared light source with a

wavelength of 880 nm. With the images captured using the RS-3000 Advance, the shape, structure, and evidence of pathology of the fundus and retina can be observed.

The RS-3000 Advance is comprised of a main body for capturing images, a computer (hereafter called PC) for storing and analyzing captured images, and an isolation transformer. The RS-3000 Advance offers the following features:

- High-speed OCT imaging for image capture that is resistant to the effect of subtle eye movements during eye fixation
- High-quality OCT imaging by creating an averaged image from multiple images captured using high-speed OCT imaging
- Simultaneous capture of SLO and OCT images for accurate and easy alignment to the fundus
- Fundus auto focusing, OCT image position detection function, and auto polarization function
- Automatic alignment to and capture of previously captured parts of the fundus
- Easy operation and image capture using the control panel of the main body or the PC mouse
- The tracing HD feature provides the averaged OCT image which uses the greater number of the images than the normal HD scan. This function is available in Macula Line scan only.
- OCT sensitivity setting (Regular/Fine/Ultra-fine) enables users to use different exposure time of the line CCD camera for OCT imaging.

**NIDEK CO., LTD.**
34-14, Maehama, Hiraishi-cho, Gamagori, Aichi 443-0038, Japan
Manufacturers, Exporters & Importers of Ophthalmic Instruments, and Opto-Electronics Instruments

TEL +81-533-67-6611
FAX +81-533-67-6610
URL http://www.nidek.co.jp
http://www.nidek.com

## INDICATIONS FOR USE – RS-3000 ADVANCE

The Nidek Optical Coherence Tomography RS-3000 Advance, including scanning laser ophthalmoscope function with Image Filing Software NAVIS-EX is a non-contact system for imaging the fundus and for axial cross sectional imaging of ocular structures. It is indicated for in vivo imaging and measurement of:

- the retina, retinal nerve fiber layer, and optic disc, and
- the anterior chamber and cornea (when used with the optional auxiliary anterior chamber adapter),

as an aid in the diagnosis and management of adults having or suspected of having ocular disease.

## INDICATIONS FOR USE – RS-3000 – PREDICATE DEVICE

The Nidek Optical Coherence Tomography RS-3000 Advance, including scanning laser ophthalmoscope function with Image Filing Software NAVIS-EX is a non-contact system for imaging the fundus and for axial cross sectional imaging of ocular structures. It is indicated for in vivo imaging and measurement of:

- the retina, retinal nerve fiber layer, and optic disc, and
- the anterior chamber and cornea (when used with the optional auxiliary anterior chamber adapter),

as an aid in the diagnosis and management of adults having or suspected of having ocular disease.

## SUBSTANTIAL EQUIVALENCE

The Nidek Optical Coherence Tomography RS-3000 Advance, with Image Filing Software NAVIS-EX, is similar in technological characteristics, performance and has the same intended use as the predicate device. Any differences in technological characteristics between the Nidek Optical Coherence Tomography RS-3000 Advance with Image Filing Software NAVIS-EX and the predicate device do not raise any new questions of safety or effectiveness. Thus, the RS-3000 Advance with Image Filing Software NAVIS-EX are substantially equivalent to the predicate device.

**NIDEK CO., LTD.**
34-14, Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, Japan
Manufacturers, Exporters & Importers of Ophthalmic Instruments, and Opto-Electronics Instruments

TEL +81-533-67-6611
FAX +81-533-67-6610
URL http://www.nidek.co.jp
http://www.nidek.com

## COMPARISON TABLE OF TECHNOLOGICAL CHARACTERISTICS

| DIFFERENCES AND SIMILARITIES CHART RS-3000 VS RS-3000 ADVANCE | | | |
|---|---|---|---|
| Model / Specifications | | **NIDEK RS-3000** | **NIDEK RS-3000 Advance** |
| Measurement principle | | Confocal scanning laser opthalmoscopy<br><br>Spectral Domain OCT | Same |
| Scan rate | | In alignment:<br>10fps for both SLO and OCT<br>In OCT image capture:<br>53,000 A-Scan/s | In alignment:<br>30fps for OCT and 12fps for SLO<br>In OCT image capture:<br>53,000 A-Scan/s |
| Light source wavelength | | SLO: 785 nm | Same |
| | | OCT: 880 nm<br>Internal fixation target: 637 nm<br>External fixation lamp: 630/565 nm | Same |
| Optical resolution | | | |
| | Fundus image capture | SLO:<br>25 μm (in the X and Y directions) | Same |
| | | OCT:<br>20 μm (in the X and Y directions), 7 μm (in the Z direction, Eye interior) | Same |
| | Anterior segment image capture | SLO:<br>50 μm (in the X and Y directions) | Same |
| | | OCT:<br>20 μm (in the X and Y directions), 7 μm (in the Z direction, Eye interior) | Same |
| Display resolution | | | |
| | Fundus image capture | SLO:<br>7.5 μm or less (in the X and Y directions) | Same |
| | | OCT:<br>3 μm or less (in the X and Y directions), 4 μm (in the Z direction, eye interior) | Same |
| | Anterior segment image capture | SLO:<br>20 μm or less (in the X and Y directions) | Same |

**NIDEK CO., LTD.**
34-14, Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, Japan
Manufacturers, Exporters & Importers of Ophthalmic Instruments, and Opto-Electronics Instruments

TEL +81-533-67-6611
FAX +81-533-67-6610
URL http://www.nidek.co.jp
http://www.nidek.com

| DIFFERENCES AND SIMILARITIES CHART RS-3000 VS RS-3000 ADVANCE | | | |
|---|---|---|---|
| Specifications \ Model | | **NIDEK RS-3000** | **NIDEK RS-3000 Advance** |
| | | OCT:<br>2 μm or less (in the X and Y directions), 4 μm (in the Z direction, eye interior) | Same |
| Working distance | | | |
| | Fundus image capture | 35.5 mm (from objective lens to eye position) | Same |
| | Anterior segment image capture | 14 mm (from the anterior segment adapter to the cornea) | Same |
| Minimum pupil diameter required | | φ2.5 mm (φ3 mm or more is recommended.) | Same |
| LCD display | | 8.4-inch TFT color LCD | Same |
| Image visibility compensation range | | −15 D to +10 D | Same |
| Angle of view in capturing | | | |
| | Fundus image capture | SLO image: 40 × 30 degree (Zoom: 20 × 15 degree) | Same |
| | | OCT image: Scan width: 3 mm to 9 mm, Scan depth: 2.1 mm | Same |
| | Anterior segment image capture | SLO image: 14 mm×12 mm | Same |
| | | OCT image: Scan width: 2 mm to 8 mm, Scan depth: 2.1 mm | Same |
| Vertical movement of main body | | 32 mm or more | Same |
| Horizontal movement of main body | | Back and forth: 40 mm or more<br>Right and left: 85 mm or more | Same |
| Vertical movement of chinrest | | 62 mm or more | Same |
| Interface function | | Main body: USB (specialized for program update)<br>PC: USB, Ethernet, eSATA | Same |
| Integration time for OCT | | REGULAR | REGULAR / FINE / ULTRA FINE |

**NIDEK CO., LTD.**
34-14, Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, Japan
Manufacturers, Exporters & Importers of Ophthalmic Instruments, and Opto-Electronics Instruments
TEL +81-533-67-6611
FAX +81-533-67-6610
URL http://www.nidek.co.jp
http://www.nidek.com

| DIFFERENCES AND SIMILARITIES CHART RS-3000 VS RS-3000 ADVANCE | | |
|---|---|---|
| Specifications \ Model | **NIDEK RS-3000** | **NIDEK RS-3000 Advance** |
| Choroidal mode | Not available | Available |
| Tracing HD | Not available | Available (only for Macula line mode) |
| Power specifications | | |
| Power supply | AC 100 V (±10%) / AC 120 V (±10%) / AC 230 V (±10%), 50/60 Hz | Same |
| Maximum allowable output | Isolation transformer, 1000 VA | Same |
| Power consumption | Main body: 300 VA, PC: 513 VA or less, PC monitor: 60 VA | Same |
| Dimensions | Main body:<br>380 mm (W) × 524 mm (D) × 499 to 531 mm (H)<br>Isolation transformer:<br>142 mm (W) × 564 mm (D) × 239 mm (H)<br>Motorized Optical Table:<br>592 mm (W) × 472 mm (D) × 596 to 794 mm (H) | Main body:<br>380 mm (W) × 524 mm (D) × 499 to 531 mm (H)<br>Isolation transformer:<br>142 mm (W) × 564 mm (D) × 239 mm (H)<br>Motorized Optical Table:<br>639 mm (W) × 472 mm (D) × 600 to 850 mm (H) |
| Mass | Main body: 34 kg<br>Isolation transformer: 15 kg<br>PC (Except for monitor): 18 kg<br>Motorized Optical Table: 27 kg | Main body: 34 kg<br>Isolation transformer: 18 kg<br>PC (Except for monitor): 18 kg<br>Motorized Optical Table: 28kg |

## CLINICAL PERFORMANCE SUMMARY

Results show that the measurements of full retinal thickness, inner retinal thickness, outer retinal thickness, and RNFL thickness with the different OCT sensitivity settings in RS-3000 Advance are similar to the thickness measurements of RS-3000.

All mean differences are within the repeatability limits of RS-3000 (K121622). This indicates that the 3 sensitivities of RS-3000Advance are equivalent to RS-3000.

**NIDEK CO., LTD.**
34-14, Maehama, Hiraishi-cho, Gamagori, Aichi 443-0038, Japan
Manufacturers, Exporters & Importers of Ophthalmic Instruments, and Opto-Electronics Instruments

TEL +81-533-67-6611
FAX +81-533-67-6610
URL http://www.nidek.co.jp
http://www.nidek.com

## NON-CLINICAL PERFORMANCE SUMMARY

The Nidek Optical Coherence Tomography RS-3000 Advance, with Image Filing Software NAVIS-EX, was evaluated according to the requirements of FDA recognized consensus standards (IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 62304, IEC 62366, ISO 15004-1, and ISO15004-2) and was found to meet the requirements of the applicable parts.

Analysis of measurement errors in each result maintains sufficient accuracy with the device requirement specification of ± 5% accuracy of thickness measurements. As a result of this testing, the RS-3000 Advance was found to maintain sufficient accuracy and to meet requirement specifications.

## CONCLUSION

In summary, Nidek Co., Ltd., is of the opinion that the Nidek Optical Coherence Tomography RS-3000 Advance, with Image Filing Software NAVIS-EX, 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 Nidek Optical Coherence Tomography RS-3000 Advance, with Image Filing Software NAVIS-EX, is substantially equivalent to the predicate device.

This summary of the 510(k) premarket notification for the NIDEK Optical Coherence Tomography RS-3000 Advance is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR§807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 19, 2014

Nidek Co., Ltd
% Ms. Lena Sattler
Orasi Consulting, LLC
2856 Whispering Shores Dr.
Vermilion, OH 44089

Re: K132323
Trade/Device Name: Nidek RS-3000 Advance
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO
Dated: January 14, 2014
Received: January 13, 2014

Dear Ms. Sattler:

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 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. 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,

Kesia Y. Alexander -S

for 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

INDICATIONS FOR USE STATEMENT: RS-3000 ADVANCE

510(k) Number (if known): K132323

Device Name: RS-3000 Advance

Indications for Use:

The Nidek Optical Coherence Tomography RS-3000 Advance, including scanning laser ophthalmoscope function with Image Filing Software NAVIS-EX is a non-contact system for imaging the fundus and for axial cross sectional imaging of ocular structures. It is indicated for in vivo imaging and measurement of:

- the retina, retinal nerve fiber layer, and optic disc, and
- the anterior chamber and cornea (when used with the optional auxiliary anterior chamber adapter),

as an aid in the diagnosis and management of adults having or suspected of having ocular disease.

Prescription Use X 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)

Charles Chiang -S
2014.02.18 09:58:38 -05'00'