JUN 2 0 2014 K133062

INNOVATIVE VISUAL SYSTEMS, LLC

510(k) Summary

Submitter Information

A.	Company Name:	Innovative Visual Systems
B.	Company Address:	386 North York Road Suite 209 Elmhurst, IL 60126
C.	Company Phone / Fax:	(T) 630.530.9700 (F) 630.530.1636
D.	Contact Person:	Donald R. Sanders, MD, PhD. Innovative Visual Systems
E.	Date Summary Prepared:	May 7, 2014

Device Identification

A.	Regulation:	21 CFR 886.1850
B.	Classification:	Class II
C.	Product Codes:	HJO, MMQ, HKO
D.	Common Device Name:	AC-Powered Slit-lamp Biomicroscope
E.	Trade / Proprietary Name:	Discovery System

Substantial Equivalence:

A comparison of the intended use, clinical applications and technological characteristics of the Discovery System and the predicate devices has been performed. The results of this comparison demonstrates that the Discovery System is substantially equivalent to the marketed predicate devices.

Predicate Device	Manufacturer	510(k) Number	Date Cleared
OPD-Scan™	Nidek Inc.	K003299	3/9/01
Slit Lamp BM 900	Haag-Streit	K100202	. 3/19/2010

Description of the Device:

The Discovery System combines a corneal topographer and an ocular wavefront aberrometer into a single, efficient system. The Discovery System combines several features to provide clinicians with detailed ophthalmic measurements. The Discovery System is designed to quickly and easily capture:

- Anterior corneal topography
- Ocular wavefront aberrations
- Retro-illumination images
- Iris images

Using near infrared (NIR) light sources for both the corneal topography and ocular wavefront aberrations permits these measurements to be taken simultaneously along the same optical axis. Retro-illuminated imaging is provided using a NIR light source reflected off the retina and optional white light and/or NIR anterior eye light sources. Iris images are captured during a retro-illumination acquisition and can optionally be captured during all other exam type acquisitions to identify eye rotations between examinations.

Indications for Use:

The Discovery System is intended for use in:

- Mapping the lower and higher order aberrations of the eye which includes measurement of the spherical power, cylindrical power and cylinder axis.
- The measurement and analysis of corneal curvature (corneal refractive power), cylindrical power, and cylinder axis of the cornea. The device also maps the display of the corneal shape.
- White-to-white measurements (also called WTW or horizontal corneal diameter).
- Retro-illumination imaging of the anterior segment of the eye including intraocular lens imaging.
- The measurement of pupil diameter.
- In the automated measurement and analysis of refractive errors of the eye including hyperopia and myopia from -25.0 to +15.0 diopters spherical, and astigmatism from 0.0 to ± 10.0 diopters.

Performance Data:

The performance data indicate that the Discovery System meets all specified requirements.

Light source power measurements were made for all three light sources (at maximum power output by our instrument) at the corneal plane. To evaluate safe light levels for the NIR SLD we used levels specified in ANSI 136.1 and ISO 15004-2. To evaluate safe light levels for the NIR LEDs we used levels specified in IEC 62471 and ISO 15004-2. To evaluate safe light levels for the White LEDs we used levels specified in IEC 62471 and ISO 15004-2. To evaluate safe light levels for combinations of the light sources we used ISO 15004-2.

System measurement performance was evaluated using bench testing. This testing consisted of designing and producing surfaces on a high-precision contact lens lathe for system calibration, corneal topography measurements, and ocular wavefront measurements.

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

June 20, 2014

Innovative Visual Systems
Donald R. Sanders, M.D. Ph.D.
Manager
386 N. York Road, Suite 209
Elmhurst, IL 60126

Re: K133062
Trade/Device Name: Discovery System
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slit lamp biomicroscope
Regulatory Class: Class II
Product Code: HJO, MMQ, HKO
Dated: May 7, 2014
Received: May 9, 2014

Dear Dr. Sanders:

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,

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

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)*
K133062

Device Name
Discovery System

Indications for Use *(Describe)*
The Discovery System is intended for use in:

-Mapping the lower and higher order aberrations of the eye which includes measurement of the spherical power, cylindrical power and cylinder axis.

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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)*

Ka N. To -S Date: 2014.06.17 11:20:14 -04'00'

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