JUL - 8 2011

RHA SUMMARY

Annidis Health Systems Corp.,
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Tel: 613.596.1800 Fax: 613.596.9453

510(k) Number K 111531

1. Sponsor Information

Applicant Name:	Annidis Health Systems Corp. 2650 Queensview Drive, Suite 245, Ottawa, Ontario, K2B 8H6, Canada Tel: 613.596.1800; Fax: 613.596.9453 Email: mmcdonnell@annidis.com
Contact Person:	Michael R McDonnell Annidis Health Systems Corp. 2650 Queensview Drive, Suite 245, Ottawa, Ontario, K2B 8H6, Canada Tel: 613.596.1800 Ext 2019; Fax: 613.596.9453 Email: mmcdonnell@annidis.com
Date of Summary:	Mar 31st, 2011

2. Device Name and Classification

Common Name:	RHA Multi-spectral Digital Ophthalmoscope
Trade Name:	RHA
Model:	RHA2020-U
Classification Name (Primary):	CFR Classification section 886.1570 (HLI)
Classification Name (Secondary):	CFR Classification section 886.1120 (HKI)
Classification:	Class II medical device

3. Predicate Devices:

The RHA multi-spectral digital ophthalmoscope is substantially equivalent to a combination of the following predicate devices:

510(k) No.	Trade Name	Product Code(s)
K983999	Panoramic 200 Ophthalmoscope	HLI
K072259	Ophthalmoscope F-10	MYC
K092056	Smartscope M3-1 EY1	HKI

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4. Device Description:

The Annidis RHA2020U multi-spectral digital ophthalmoscope which presents eye care practitioners (optometrists and ophthalmologists) with a series of retinal spectral images from each eye of a patient. The images each have a spatial resolution of over four million pixels spread over a visual range of greater than 40 degrees. The instrument also captures an image of the iris and pupil.

The device is arranged in four major hardware subcomponents and one remote software component used for clinical visualization and tracking purposes. The four hardware components are listed below:

- The Optical Head Unit (OHU) contains the camera and the illuminating LEDs and is aligned to the eye of the sitting patient whose head is stabilized using a chin-rest and forehead brace. The OHU contains the optical and electrical systems required to capture images of the eye and the means to align the patient with the device.
- The Host Computer (HC), a Linux-based host computer that serves as the operator interface.
- The Universal Power Supply (UPS), a custom designed power supply receives power from the AC mains and supplies power using low voltage DC to the host computer, the display, and the optical head unit (OHU).

The Touch Screen Display, that displays information from the host computer, configures the optical head unit for patient comfort, visualizes the patient data and triggers image capture.

5. Intended Use:

The Annidis RHA2020-U multi-spectral digital ophthalmoscope is intended to capture images of the fundus of the eye which can be used to assist in diagnosis and observation of fundus diseases

6. Predicate Devices:

The Annidis retinal health assessment device is substantially equivalent to a combination of the following predicate devices:

- The Optos Panoramic 200 (K983999) is a scanning laser ophthalmoscope (SLO). It uses a laser as a light source that is scanned by a deflection system in two axes across the retina of the eye to generate a colour image. The returned light then travels back along the same path to a light detector that converts the light to an electrical signal. The electrical signal is digitized and used to build up an

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electronic picture in a personal computer and displayed either on a cathode ray tube or on a liquid crystal display.

- The Nidek Ophthalmoscope F-10 (K072259) is categorized as a Class I 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.

- The Optomed Smartscope M3-1 EY1 (K092056) is a hand-held digital ophthalmoscope used to capture digital images and video of the cornea, aqueous, lens, vitreous and retina of the human eye. M3-1 EY1 has a LED light source. Image data is stored on the Flash memory card using 6.6 megapixel CMOS sensor and transferred to the PC by using USB connection. The device has rechargeable batteries.

	Annidis RHA	**Nidek F-10**	**Optos P200**	**Optomed Smartscope 3M-1 EY1**
field of view (degrees)	42	40	>90	30
physical configuration	tabletop with headrest	tabletop with headrest	stand alone and patient manipulation	handheld
spectral range covered	green-near infrared	blue-near infrared	green & red	visible
number of spectral bands	6	4	2	~3
type of source	LED	laser	laser	LED
image construction process	imaging	scan	scan	imaging
indicated for retinal imaging	yes	yes	yes	yes
viewing software	software accessory	medical device (NAVIS)	software accessory	software accessory
product classification	CFR 886.1570	CFR 886.1570	CFR 886.1570	CFR 886.1120
product code	HLI (primary) HKI(Secondary)	MYC (could also be HLI)	HLI	HKI

Table 5-1: Table of similarities between the RHA and the predicate devices

7. Comparison with Predicate Devices

Substantial equivalence of the Annidis RHA Multi-Spectral Ophthalmoscope is addressed relative to three legally marketed predicate devices. The Nidek F-10 and the Optos P-200 are scanning laser ophthalmoscopes, and the Optomed Smartscope is a

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handheld digital ophthalmoscope. The data set available for the predicate device parameters has been compared to the similar data for the RHA to provide evidence for the substantial equivalence of the RHA to the legally marketed devices. Based on the data and comparisons presented in this section, the RHA is substantially equivalent to the legally marketed predicate devices. It is similar in characteristics, materials, has similar technological features, intended use and indications for use as the predicates, and does not raise any new questions of safety and effectiveness.

8. Performance Standards:

No applicable performance standards have been issued under the Food, Drug and Cosmetic Act.

The RHA retinal health assessment device has been tested by an accredited third party test laboratory and conforms to the following voluntary standards:

- IEC 60601-1:1988 Medical Electrical Equipment; Part 1: General Requirements for Safety + A1:1991 and A2:1995, including Appendix – National Deviations – Test Results according to ONLINE CB BULLETIN as of June 2009.

- IEC60601-1-1:2000 Medical Electrical Equipment - Part 1: General Requirements For Safety 1: Collateral Standard: Safety Requirements for Medical Electrical Systems, 2nd Edition.

- IEC 60601-1-2:2001 Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests + A1:2004

- ISO 15004-2:2007 Ophthalmic Instruments - Fundamental Requirements and Test Methods – Part 2: Light Hazard Protection.

- UL 60601-1 (first Edition, 2003): Medical Electrical Requirements Part 1: General requirements for Safety.

- IEC60950-1 (First Edition 2001) A11:2004: Information Technology Equipment – Safety- Part 1: General Requirements.

- CAN / CSA C22.2 No. 601.1-M90 Medical Electrical Equipment - Part 1: General Requirements for Safety (Adopted IEC 601-1, Amendment 1:1991)

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9. Non-Clinical Performance Summary:

Annidis Health Systems Corp. has verified and validated that the RHA Multi-Spectral Digital Ophthalmoscope meets its functional specifications and performance requirements.

The requirements for the RHA are set out in the Product Requirements Specifications, and addressed by Performance Testing Reports and are illustrated through the use of Performance Traceability Matricies. The RHA is controlled mostly by software and firmware to which performance testing was conducted. The test management process used was an industry off-the-shelf validated management tool.

The RHA2020-U Multi-Spectral Digital Ophthalmoscope was subjected to Performance Testing and the image output of the RHA2020-U device was compared with two predicate devices. The results of Performance Testing demonstrates substantial equivalence between the image output (i.e.: subject digital images captured) of the two selected predicate devices and those of the digital images captured using the RHA2020-U device when reviewed by the Performance Test Investigator. Submitted data included:

- Digital images evaluated from digital scan output taken of non-mydriatic eyes of human subjects.
- Digital images evaluated from digital scan output taken of mydriatic eyes of human subjects.

It is concluded that in a direct comparison of images between subject and predicate devices, that the images are comparable and meet performance requirements for acceptance and the intended use.

The RHA Multi-Spectral Ophthalmoscope complies with applicable U.S. and international electrical, electromagnetic compatibility and light safety standards (as outlined above) for products of its kind.

10. Conclusions

Based on the information contained in this submission, similarity to the predicate devices (the Optos Panoramic 200, the Nidek Ophthalmoscope F-10, and the Optomed Smartscope M3-1 EY1), and the results of our design control activities and non-clinical performance testing, has been established.

In summary, Annidis Health Systems Corp. believes that the RHA Multi-Spectral Ophthalmoscope is as effective, and performs as well as devices currently on the market, and concludes that the RHA Multi-Spectral Ophthalmoscope is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUL - 8 2011

Annidis Health Systems Corp.
c/o William Sammons
Third Party Reviewer
Intertek Testing Services NA, Inc.
2307 E. Aurora Rd. Unit B7
Twinsburg, OH 44087

Re: K111531
Trade/Device Name: RHA Multi-spectral Digital Ophthalmoscope Model RHA2020-U
Regulation Number: 21 CFR 886.1570
Regulation Name: Opthalmoscope
Regulatory Class: Class II
Product Code: HLI and HKI
Dated: June 1, 2011
Received: June 2, 2011

Dear Mr. Sammons:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Alexander

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: RHA2020-U multi-spectral digital ophthalmoscope

Indications for Use:

The Annidis RHA2020-U multi-spectral digital ophthalmoscope is intended to capture images of the fundus of the eye which can be used to assist in diagnosis and observation of fundus diseases.

Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K111531