July 27, 2018

Ilooda Co., Ltd.
% Mina Joo
Assistant Manager
BT Solutions, Inc.
Unit 502, 148 Yeoksam-ro Gangnam-gu
Seoul, 06249 Republic of Korea

Re: K173474
Trade/Device Name: RetiCapture
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: June 6, 2018
Received: June 8, 2018

Dear Mina Joo:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bradley S. Cunningham -A

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)*
K173474

Device Name
RetiCapture

Indications for Use *(Describe)*
RetiCapture is a digital hand-held (portable) eye-fundus camera used to record digital photographs and video of fundus of the human eye and surrounding area.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(k) Summary

1. General Information

Applicant/Submitter:	ILOODA Co., Ltd.
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Contact Person:	Mina Joo, BT Solutions, Inc.
Address:	Unit 502, 148 Yuksamro, Gangnam-gu, Seoul, Republic of Korea Tel) +82.2.538.9140 Email) smanager@btsolutions.co.kr
Preparation Date:	July-24-2018

2. Device Name and Code

Device Trade Name:	RetiCapture
Common Name:	Ophthalmic Camera
Classification Name:	Ophthalmic camera
Product Code:	HKI
Regulation Number:	886.1120
Classification:	Class II
Review Panel:	Ophthalmic

3. Predicate Devices

RetiCapture is substantially equivalent to the following devices

Table 5.1 Predicate devices

Applicant	Device Name	510(k) Number
Medimaging Integrated Solution Inc.	MiiS Horus Scope DEC 100	K120982

4. Device Description

RetiCapture is a hand-held digital ophthalmic camera that together with the optics modules used to capture digital images and video of fundus and surrounding area of the human eye. RetiCapture has an LED light source visible white light and infrared light. Light target LED's are used to eye position fixation during imaging. Image data is stored on the Flash memory card using 5 mega-pixel CMOS sensor and transferred to the PC by using USB connection. Device has rechargeable battery.

5. Indications / Intended Use

RetiCapture is a digital hand-held (portable) eye-fundus camera used to record digital photographs and video of fundus of the human eye and surrounding area.

6. Technical Characteristics in Comparison to Predicate Devices

RetiCapture is substantially equivalent to the following legally marketed predicate devices

	Predicate Device	**Proposed Device**
510(K) Number	K120982	K173474
Manufacturer	Medimaging Integrated Solution Inc.	ILOODA CO., LTD
Device Name	MiiS Horus Scope DEC 100	RetiCapture
Clearance Date:	Sep 17,2012	N/A
Classification / Regulation	Class II/21 CFR 886.1120 Ophthalmic Camera	Class II/21 CFR 886.1120 Ophthalmic Camera
Product Code	HKI	HKI
Intended Use/ Indications for Use	MiiS Horns Scope DEC 100 is a digital hand-held eye-fundus camera used to record digital photographs and video of fundus of the human eye and surrounding area	RetiCapture is a digital hand-held(portable) eye-fundus camera used to record digital photographs and video of fundus of the human eye and surrounding area
Intended for	Prescription Use	Prescription Use
Observation light Source	white & IR LED	white & IR LED
Diopter	-20D ~ +20D	-20D ~ +20D
FOV (Field of view)	40°	50°
Resolutions	1920x1080	3072x1728
Storage media	SD CARD	SD CARD
Image data format	JPEG (Still picture) H.264(Video)	JPEG (Picture), Full HD (Video)
LCD Display	3.5” full color LCD	5” full color TFT-LCD
Power	Rechargeable Li-ion battery 3.7V	Rechargeable Li-ion battery 3.7V

7. Performance Data

Non-clinical tests: Measurement of Photobiological safety of lamps and lamp systems were performed. Other performance, such as electromagnetic compliance, and etc, were tested using following consensus standards:

- Basic safety and essential performance of the RetiCapture is tested and evaluated according to IEC 60601-1:2005 (Third Edition) + CORR.1:2006 + CORR.2:2007 + A1:2012. All the results presented here demonstrated general requirements for basic safety and essential performance.
- Effect to the device by electromagnetic disturbances were tested and evaluated according to EN 60601-1-2:2007. All the results presented here demonstrated the requirements and tests for electromagnetic disturbances.
- Photobiological safety of lamps and lamp systems of medical devices is evaluated according to FDA-recognized consensus standard, IEC 62471:2006 (First Edition). All the results presented here demonstrated the Photobiological safety of lamps and lamp systems of the RetiCapture.
- Risk management was recorded by referring to ISO 14971:2012.
- Fundamental requirements and test methods for light hazard protection of RetiCapture is evaluated according to FDA-recognized consensus standard, ISO 15004-2 First Edition.
- Extensive software testing and validation have been conducted to ensure that RetiCapture performs to acceptable level, repeatedly and reliably referring to consensus standard IEC 62304:2006 and ISO 14971:2012.
- Ophthalmic instruments of RetiCapture were tested and evaluated according to FDA-recognized consensus standard ISO 10940:2009.

8. Substantial Equivalence

The intended use of the RetiCapture is within the scope of the predicate device. RetiCapture, from both a design and clinical perspective, uses similar or identical technology as the cited predicate device and has the same intended uses. Based upon the overall performance characteristics for the RetiCapture, ILOODA Co., Ltd., believes that no significant differences exist in usage of its underlying technological principles between RetiCapture and the cited predicate device.

9. Conclusions

On the basis of the information provided in this Summary, ILOODA Co., Ltd., believes that RetiCapture is substantially equivalent to legally commercialized predicate device for the purposes of this 510 (k) submission.