February 23, 2018

Canon Inc. - Medical Equipment Group
% Ryan Bouchard
Director Medical Devices
Ora, Inc.
300 Brickstone Square
Andover, MA 01810

Re: K173689
Trade/Device Name: Ophthalmic Software Platform RX
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: NFJ
Dated: December 21, 2017
Received: December 26, 2017

Dear Ryan Bouchard:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 yours,

Bradley S. Cunningham -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Ophthalmic Software Platform RX

Indications for Use *(Describe)*
The Ophthalmic Software Platform RX is an ophthalmic software system indicated for acquiring, storing, managing, processing, and display of patient, diagnostic, image data from Canon's mydriatic and non-mydriatic retinal cameras.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

This summary of the 510(k) premarket notification for the Canon Ophthalmic Software Platform RX is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

a. Owner Company name, address

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b. Contact/Application Correspondent

Ryan Bouchard
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300 Brickstone Square
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E-mail: rbouchard@oraclinical.com

c. Date Prepared

February 23, 2018

d. Name of Device

Trade Name:	Ophthalmic Software Platform RX
Common Name:	System, Image Management, Ophthalmic
Classification Name:	Picture archiving and communication systems
Classification Regulation:	21 CFR 892.2050

e. Predicate Devices

The Ophthalmic Software Platform RX is substantially equivalent to the Topcon IMAGEnet 5 PC Software System (K132438).

f. Device Description

The Ophthalmic Software Platform RX is an ophthalmic software system indicated for acquiring, storing, managing, processing, and display of patient, diagnostic, image data from Canon's mydriatic and non-mydriatic retinal cameras.

The Ophthalmic Software Platform RX consists of three types of software including the RX Capture for Retinal Camera, RX Server and RX Viewer.

RX Capture for Retinal Camera software

This is a software executed on a Capture PC. This software acquires images from a retinal camera that the control software captures and puts on the Capture PC. This software acquires images of eye, stores images and processes images. Also, this software displays acquired and processed images which are stored in a Server's database.

RX Viewer software

This is a software executed on a Viewer PC. This software processes images and displays acquired and processed images which are stored on the RX Capture for Retinal Camera or RX Server's database.

RX Server software

This is a software executed on a Viewer PC. This software stores images, processes images and displays acquired and processed images which are stored in its' own database.

g. Indications for Use

The Ophthalmic Software Platform RX is an ophthalmic software system indicated for acquiring, storing, managing, processing, and display of patient, diagnostic, image data from Canon's mydriatic and non-mydriatic retinal cameras.

h. Statement of Substantial Equivalence

Canon's Ophthalmic Software Platform RX is substantially equivalent to the IMAGEnet 5 cleared in K132438. As explained in more detail below, the Ophthalmic Software Platform RX has the same intended use and similar indications for use, similar principles of operation, and similar technological characteristics as the previously cleared predicate device**.**

The Ophthalmic Software Platform RX has an intended use, which is the same as the predicate device. Both the Ophthalmic Software Platform RX and the predicate device are indicated for acquisition, storage and

management of digital images, patient data and diagnostic data from computerized diagnostic instruments.

The Ophthalmic Software Platform RX and the predicate device are both ophthalmic picture archiving and communications systems that collect, store, and manage digital images of the eye. Both the Ophthalmic Software Platform RX and the predicate device can be used with both mydriatic and non-mydriatic retinal cameras. Both software devices support color, FA and FAF images while IMAGEnet 5 also supports ICG images. This minor difference between the devices does not impact the safety or effectiveness of the Ophthalmic Software Platform RX.

The minor differences between the subject device and the predicate devices do not raise new questions of safety or effectiveness. The Ophthalmic Software Platform RX is as safe and effective as its predicate devices, and thus, may be considered substantially equivalent.

i. Software Verification and Validation

Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

j. Conclusions

Canon's Ophthalmic Software Platform RX is as safe and effective as the previously cleared IMAGEnet 5 (K132438). The Ophthalmic Software Platform RX has the same intended use and similar indications for use, similar principles of operation, and similar technological characteristics as the previously cleared predicate device and is therefore substantially equivalent**.**