September 25, 2020

Ryan Bouchard, Official Correspondent
o/b/o Canon Inc.
9-1, Imaikami-cho
Nakahara-ku, Kawasaki, Kanagawa 211-8501
Japan

Re: K201273
Trade/Device Name: ImageSPECTRUM
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: NFJ
Dated: July 31, 2020
Received: August 5, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K201273

Device Name
imageSPECTRUM V6

Indications for Use *(Describe)*
The imageSPECTRUM V6 is an ophthalmic software system indicated for acquiring, storing, managing, processing, and display patient, diagnostic and image data from Canon digital retinal cameras. It is also indicated for review of patient, diagnostic and image data and measurement by trained healthcare professional.

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.

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510(k) Summary

Submitter
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Date prepared
July 29, 2020

Submission type
Traditional 510(k)

Name of Device
Trade Name: imageSPECTRUM V6
Common Name: Picture archiving and communications systems.
Classification Name: System, Image Management, Ophthalmic
Classification Regulation: 892.2050
Product Code: NFJ

Predicate Device
Ophthalmic Software Platform RX (K173689)

Reference Device
CR-2 Plus AF (K123208)

Device Description
The imageSPECTRUM V6 is an ophthalmic imaging software for acquiring, storing, managing, processing and displaying patient, diagnostic and image data from Canon digital retinal cameras. The imageSPECTRUM V6 consists of three software; iS Capture, iS Review, and iS Server. The "iS Capture" has functions to communicate with Canon's retinal camera to take retinal images. The "iS Review" has functions for displaying, processing, and transferring retinal images. The "iS Server" has functions for storing and archiving retinal images.

The imageSPECTRUM V6 is an ophthalmic software system indicated for acquiring, storing, managing, processing, and display patient, diagnostic and image data from Canon digital retinal cameras. It is also indicated for review of patient, diagnostic and image data and measurement by trained healthcare professional.

Statement of Substantial Equivalence

Canon Inc.'s imageSPECTRUM V6 is substantially equivalent to Canon Inc.'s Ophthalmic Software Platform RX cleared in K173689 and the reference device, Canon Inc.'s CR-2 PLUSAF cleared in K123208**.** imageSPECTRUM V6 has the same intended use and similar indications for use, similar principles of operation, and similar technological characteristics as the previously cleared predicate device**.** See **Table 1** for a substantial equivalence chart comparing the similarities and differences between imageSPECTRUM V6 and the predicate and reference. Thus, imageSPECTRUM V6 is substantially equivalent to its predicates.

Table 1
imageSPECTRUM V6 Substantial Equivalence Table

		Proposed Device	Predicate Device	Reference Device
Model		imageSPECTRUM V6 (iS Review V6.0, iS Capture V6.0, iS Server V6.0)	Ophthalmic Software Platform RX (RX Capture for Retinal Camera, RX Server, RX Viewer)	CR-2 PLUSAF (Retinal imaging control software)
510(k) Submitter [Number]		Canon Inc. [K201273]	Canon Inc. [K173689]	Canon Inc. [K123208]
Product Code and Classification		NFJ 21CFR 892.2050	NFJ 21CFR 892.2050	HKI 21CFR 886.1120
Indications for Use		imageSPECTRUM V6 is an ophthalmic software system indicated for acquiring, storing, managing, processing, and display of patient, diagnostic and image data from Canon digital retinal cameras. It is also indicated for review of patient, diagnostic and image data and measurement by trained healthcare professional.	The Ophthalmic Software Platform RX is an ophthalmic software system indicated for acquiring, storing, managing, processing, and display of patient, diagnostic and image data from Canon digital retinal cameras. It is also indicated for review of patient, diagnostic and image data and measurement by trained healthcare professional.	The Digital Retinal Camera CR-2 Plus AF is intended to be used for taking digital images of the retina of the human eye without a mydriatic. The CR-2 Plus AF has the following photography modes: color, red free, cobalt digital and fundus autofluorescence (FAF).
User Management		Supported	Supported	Supported
Patient Management		Supported	Supported	Supported
		Backup (Archive)	Backup	Backup
		Restoration	Restoration	Restoration
Devices that are compatible		Canon's retinal cameras (CR-2 Plus AF)	Canon's retinal cameras (CR-2 AF, CR-2 Plus AF, CX-1)	Canon's retinal cameras (CR-2 Plus AF)
Type of Retinal Camera image		Color, FA, FAF	Color, FA, FAF	Color, FA, FAF
Capture Function	Communication with retinal camera's firmware	Supported	-	Supported
	Capture Sequence Control	Supported	-	Supported

		Proposed Device	Predicate Device	Reference Device
	Auto Exposure Control	Supported	-	Supported
	Auto Focus Control	Supported	-	Supported
	Auto Shot Control	Supported	-	Supported
View Image		Single View	Single View	Single View
		Comparison	Both Eyes	Both Eyes
			Comparison	Comparison
Drawing Function		Supported	Supported	Supported
Image Processing		Brightness	Brightness	Brightness
		Contrast	Contrast	Contrast
		Zoom	Zoom	Zoom
		RGB Filters	RGB Filters	RGB Filters
		Redfree	Redfree	Redfree
		Emboss	Emboss	-
		Mosaic(optional)	Mosaic(optional)	Mosaic(optional)
		Overlay	Overlay	-
Annotation		Drawing Function	Drawing Function	-
		Add text on the image	Add text on the image	-
		Cup to Disc	Cup to Disc	Cup to Disc
		Macular Grid	-	-
		PDT Marker	-	-
		PDT Counter	-	-
		AVR	-	-
		Protractor	-	-
Standalone Configuration		Supported	Supported	Unsupported
Server Client Configuration		Supported	Supported	Unsupported
DICOM Communication		Modality Worklist	Modality Worklist	Modality Worklist
		DICOM Storage Commitment	DICOM Storage Commitment	DICOM Storage Commitment
		-	MPPS	MPPS
STEREO Viewing		Supported	Supported	Supported
Printing Image		Supported	Supported	Supported
Software requirements		Microsoft Windows 10 Pro(64-bit)	Microsoft Windows 10 Pro(64-bit)	Microsoft Windows 7 Professional SP1(32-bit/64-bit)
Hardware requirements		CPU: Core-i7 2GHz or Greater, RAM: 4GB or more, Display Screen resolution: 1920x1080	CPU: Core i3 2.4GHz or Greater, RAM: 4G or More, Display: 1920x1080 pixels	CPU: Core 2 Duo 2.4 GHz or higher, RAM: 2GB or more Display: Screen resolution(1280x800pixel) or higher, Hard disk: 7,200 rpm or higher
Viewing Reports by Multiple Users		Supported	Supported	Unsupported

Summary of Differences

The differences between the proposed device and the predicate and reference devices are summarized below along with the possible effects these differences may have on safety and efficacy. For all items where either the predicate device or the reference device has a matching

function, no safety or efficacy questions are raised. The items which are unique to the proposed device are listed below:

Annotation: The **Annotation** tools can be used to label (i.e., with text), measure or bring attention to a specific area in an image. Annotation tools are present in the predicate and reference device however additional annotation tools have been added to the proposed device.

The annotation tools that have been added to the proposed device are Macular Grid, PDT Marker, PDT Counter, AVR, and Protractor.

- Macular Grid: Overlays a grid over the macula.
- PDT Marker: This tool allows the user to circumscribe a PDT lesion, recording inner and outer diameters, as well as square area.
- PDT Counter: This tool is used to size and count various lesions.
- AVR: Provides a tool to measure artery and vein diameters. Reports multiple artery to vein ratios.
- Protractor: Creates a protractor graphic on the image for easy measurement purposes.

The tools provided are to aid in viewing and measuring features within the image. There are no safety or efficacy questions raised by any of these tools. Instructions for the use of the tools are provided in the User Manual.

Performance Data
Software verification and validation was performed to ensure that the software device performed as intended.

Conclusion
Canon concluded that the Canon imageSPECTRUM V6 is substantially equivalent to the predicate devices based on identical intended use and substantially equivalent technological characteristics and the similarities in functional design.