March 3, 2020

Ophthalmic Labs, Inc.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K200275
Trade/Device Name: OVision Imaging System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: NFJ
Dated: January 30, 2020
Received: February 4, 2020

Dear Dave Yungvirt:

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,

for Tieuvi Nguyen, Ph. D.
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)*
K200275

Device Name

OVision Imaging System

Indications for Use *(Describe)*

The OVision Imaging System is a software program that is intended for use in the collection, storage, and management of digital images, patient data, diagnostic data and clinical information from computerized diagnostic imaging devices through direct connection with the instruments.

The software system is indicated for use with retinal camera or digital camera imaging devices, including retinal cameras, non-mydriatic retinal cameras, and slit lamps.

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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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**K200275**

# 510(k) Summary

**Submitted By**

Ophthalmic Labs, Inc.
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**Contact Person**

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**Date Prepared**

March 2, 2020

**Submission Type**

Traditional 510(k)

**Trade Name**

OVision Imaging System

**Common Name**

Ophthalmic Image Management System

**Classification**

Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: NFJ

**Indications for Use**

The OVision Imaging System is a software program that is intended for use in the collection, storage, and management of digital images, patient data, diagnostic data and clinical information from computerized diagnostic imaging devices through direct connection with the

instruments. The software system is indicated for use with retinal camera or digital camera imaging devices, including retinal cameras, non-mydriatic retinal cameras, and slit lamps.

**Predicate Device**

Topcon Corp.
IMAGEnet Professional PC Software System
K082364
CFR Number: 21 CFR 892.2050
Product Code: NFJ

**Description of the Device**

The OVision Imaging System is a software system that collects, stores, and maintains images of the retina and anterior segment of the eye. The Ovision Imaging System is used together with retinal cameras or digital camera imaging devices.

In operation, the retinal camera will be operated as normally intended, with the OVision Imaging System capturing images of the patient. The OVision Imaging System does not alter or control the parameters of the retinal camera.

The OVision Imaging System software accessory captures images from USB or Firewire digital cameras that are commercially available for both color and monochromatic imaging. The digital camera output of the fundus camera is tethered to the commercially available computer via a USB or FireWire cable.

The OVision Imaging System software system receives the images captured by the retinal camera or digital camera. The images are stored in the computer's random access memory (RAM) and then saved on the local storage of the computer. The patient and exam information are stored in the system's database.

The OVision Imaging System attaches directly to an existing retinal camera or digital camera via a communication cable. The user is able to operate the fundus camera in the manner it was intended, either viewing and focusing on the patient's retina through the eye piece or through the external monitor. During operation, the digital camera will transfer captured images to the computer to then store on its local drive.

**Comparison to Predicate Device**

The OVision Imaging System and the predicate device, the IMAGEnet Professional PC Software System, have the same intended use. The two software devices have the same technological characteristics. With either system, the user views the patient's retina through an existing fundus camera's eye piece or external display and operates the fundus camera as normally intended.

Both software devices have the same basic functions: image capture, display, database archival of images and image processing. The OVision Imaging System and the predicate device serve the same clinical purpose and provide the same functionality. The OVision Imaging System and the IMAGEnet Professional PC Software System are both used together with retinal cameras or digital camera imaging devices. They both capture images of the retina and anterior segment of the eye. Both provide for color and monochrome imaging modalities, image review, enhance and print capabilities, and both provide archive and retrieve functionality.

A minor technological difference between the OVision Imaging System and the predicate device is that the OVision Imaging System does not have functions to allow stitching of retinal images together or estimating the desired laser treatment size for photodynamic therapy (PDT). The minor differences do not impact substantial equivalence or patient safety, as evidenced by the fact that these functions are described as optional in the predicate device. Therefore, the OVision Imaging System and the IMAGEnet Professional PC Software System are substantially equivalent.

**Non-Clinical Performance Data**

Performance testing was performed on the OVision Imaging System during software verification and validation. During verification, the OVision Imaging System was found to meet the requirements, and during validation, the OVision Imaging System was found to perform as intended.

**Conclusions from Non-Clinical Tests**

Based upon the results of the non-clinical performance testing, the OVision Imaging System has demonstrated that it is Substantially Equivalent (SE) in safety and effectiveness to the selected predicate device.