DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 27, 2015

IRIS Intelligent Retinal Imaging Systems, LLC
Ora, Inc
Mr. Ryan Bouchard
Director Medical Devices
300 Brickstone Square
Andover, MA 01810

Re: K141922
Trade/Device Name: IRIS Intelligent Retinal Imaging System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: NFJ
Dated: January 16, 2015
Received: January 20, 2015

Dear Mr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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 Y. Alexander -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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K141922

Device Name
IRIS Intelligent Retinal Imaging System

Indications for Use *(Describe)*
The IRIS Intelligent Retinal Imaging Systems is a comprehensive web-based software system application intended for use in storing, managing, and displaying patient data, diagnostic data and images from computerized diagnostic instruments or systems. Original and color amplified images can be viewed by trained healthcare professionals.

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 IRIS Intelligent Retinal Imaging Systems is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR§807.92.

**Date Prepared:** August 15, 2014

**SPONSER/ 510(k) OWNER/ MANUFACTURER**
Intelligent Retinal Imaging Systems, LLC
P.O. Box 13272
Pensacola, FL 32591

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**NAME OF DEVICE**
Trade Name: IRIS Intelligent Retinal Imaging System
Common Name: Ophthalmic Image Management System

**DEVICE CLASSIFICATION/FDA REVIEWING BRANCH**
The Ophthalmic Branch has classified Ophthalmic Image Management Systems as Class II devices pursuant to 21 C.F.R. §892.2050.

**PRODUCT CODE: CLASSIFICATION / CFR TITLE**
NFJ, 21 CFR 892.2050

**PREDICATE DEVICES**
Optos Advance Software (K113696)
Zeiss Forum (K122938)

## INDICATIONS FOR USE

The IRIS Intelligent Retinal Imaging Systems is a comprehensive web-based software system application intended for use in storing, managing, and displaying patient data, diagnostic data and images from computerized diagnostic instruments or systems. Original and color amplified images can be viewed by trained healthcare professionals.

## PRODUCT DESCRIPTION

The IRIS software is a software as a service application that is hosted on the internet which allows clinicians the ability to scan a patient's retina with a fundus camera, transmit the images up to a website and offer an opinion on the scans. It also allows users the ability to input data relative to a visual fields exam. The combination of a fundus picture and visual fields data allows a licensed/credentialed clinician to evaluate the patient for glaucoma.

A patient presents to a provider's office where a retinal scan is ordered by a licensed provider. The patient then sits with a technician at a fundus camera where one or more images are captured of the patient's retina using flash fundus photography. The images are then exported to the Internet based application. A licensed provider then logs into the application, reviews the images, inputs their discreet opinions on a number of suspected conditions such as Diabetic Retinopathy, Macular Edema, Glaucoma, Dry MD, Wet MD, Vein Occlusion, HTN Retinopathy, Macular Hole, Epiretinal Membrane, Cataract, and others. The provider then inputs a care plan based on grading levels chosen. The results are then sent back to the client for inclusion in the patient's chart and for possible follow up.

Secondarily, a patient presents to clinician's office and a glaucoma screening is ordered. The patient then sits with a technician at a visual fields system and a visual fields examination is performed. Following the examination, if the patient has not had a recent fundus evaluation, the previous workflow is followed where a patient has flash fundus images taken of one or both eyes. Following that examination, the visual fields data is entered into the application and is saved as a new evaluation. A licensed/credentialed physician then logs into the system, reviews the data and images, inputs their discreet opinions, and finally signs the result.

The application is fully HIPAA compliant encrypting all protected health information related to a patient's demographics using an encryption key stored separately from the database specific to each clinic utilizing the service. The application should require no modification to a client's security infrastructure to transmit the images up to the IRIS system or to download a result to the patient's chart.

The application is developed on the Microsoft .NET platform stack. It utilizes the C# (c sharp) programming language to program the parts of the system that interact with backend services including the patient relational database system, client communication software, and the web front end. IRIS accepts files in DICOM and JPEG format.

**SUBSTANTIAL EQUIVALENCE**

The IRIS Intelligent Retinal Imaging Systems software is substantially equivalent to a combination of the Optos Advance Software (K113696) and the Zeiss Forum (K122938). The IRIS Intelligent Retinal Imaging Systems software has a similar intended use and indications for use, technological characteristics, and principles of operation as the previously cleared predicates. Therefore, the IRIS Intelligent Retinal Imaging Systems software is substantially equivalent to the predicate device.

The IRIS Intelligent Retinal Imaging Systems is a comprehensive web-based software system application intended for storing, managing, and displaying patient data, diagnostic data and images from computerized diagnostic instruments or systems. Original and color amplified images can be viewed by trained healthcare professionals for use in analysis of images and data. This indications for use statement is similar to the indications for use statement for the Optos Advance Software cleared in K113696 with the exception that the Optos Advance Software also handles videos and video documentation while the IRIS system does not. The indications for use statement is also similar to the indications for use statement for the Zeiss Forum cleared in K122938 with the exception that the Forum system handles images and performs measurements while the IRIS system does not perform any measurements. The IRIS Intelligent Retinal Imaging Systems has the same intended use and similar indications for use as the predicate devices and may therefore be found substantially equivalent.

The IRIS Intelligent Retinal Imaging Systems has very similar technological characteristics to the Optos Advance Software and the Zeiss Forum software. All of the systems are software only; there are no hardware components. The IRIS software and the Optos Advance Software are both web-based viewing platforms while the Zeiss Forum has an option for a local client application. All of the software products have centralized storage of images and data. All of the products support files for uploading fundus photographs and all of the software products support non-mydriatic image capture devices. All of the products perform image data management. All of the products allow for management and review of fundus images while the IRIS software and Zeiss Forum also allow management and review of visual field images. All of the products allow importing of image files and enhancement or color amplification of images.

Therefore, the technological characteristics of the IRIS Intelligent Retinal Imaging Systems software are similar to the identified predicate devices.

In summary, the IRIS Intelligent Retinal Imaging Systems software has a similar intended use as the previously cleared predicate devices. In addition, the IRIS Intelligent Retinal Imaging Systems software has similar technological characteristics and principles of operation as its predicates. Although there are differences between the IRIS Intelligent Retinal Imaging Systems and its predicate devices, those differences do not raise new questions of safety or effectiveness. Thus, the IRIS Intelligent Retinal Imaging Systems is substantially equivalent.

**PERFORMANCE DATA**

No performance data was required or provided. Software validation and verification was performed which showed that the software performed as intended supporting substantial equivalence to the predicate devices.

**CONCLUSIONS**

IRIS Intelligent Retinal Imaging Systems has the same intended use and indications for use, technological characteristics, and principles of operation as the previously cleared predicates. The minor differences between the subject device and the predicate devices so not raise new questions of safety or effectiveness. Therefore, the IRIS Intelligent Retinal Imaging Systems is substantially equivalent.