



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

February 11, 2016

Optovue, Inc.  
Mr. Edward J. Sinclair  
VP, Regulatory and Quality Affairs  
2800 Bayview Drive  
Fremont, CA 94538

Re: K153080  
Trade/Device Name: RTVue XR OCT with Avanti with AngioVue Software  
Regulation Number: 21 CFR 886.1570  
Regulation Name: Ophthalmoscope  
Regulatory Class: Class II  
Product Code: HLI, OBO  
Dated: January 13, 2016  
Received: January 14, 2016

Dear Mr. Sinclair:

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" (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.

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 Alexander

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

## Indications for Use

510(k) Number (if known): K153080

Device Name

RTVue XR OCT Avanti with AngioVue Software

Indications for Use (Describe)

The RTVue XR OCT Avanti with Normative Database is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as a tool and aid in the diagnosis and management of retinal diseases by a clinician. The RTVue XR OCT Avanti with Normative Database is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disk measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases.

The RTVue XR OCT Avanti with AngioVue Software is indicated as an aid in the visualization of vascular structures of the retina and choroid.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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## 510(k) Summary (K153080)

### Submitter Information

Company: Optovue, Inc.  
2800 Bayview Drive  
Fremont, CA 94538  
(510) 897-1575  
  
Edward J. Sinclair  
Vice President, Regulatory and Quality Affairs

Date Prepared: January 12, 2016

### Device Name and Classification

Common Name: Optical Coherence Tomography  
Proprietary Name: RTVue XR OCT Avanti with AngioVue™ Software  
Classification Name: Tomography, Optical Coherence  
Product Code: OBO, HLI  
Regulation Number: 886.1570  
Class: II

### Predicate Device

Optovue, Inc. RTVue XR OCT (K120238)

### Reference Device

Carl Zeiss Meditec, Inc. CIRRUS HD-OCT with Software Version 8 (K150977)

### Intended Use

The RTVue XR OCT Avanti with Normative Database is an optical coherence tomography system indicated for the *in vivo* imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as a tool and aid in the diagnosis and management of retinal diseases by a clinician. The RTVue XR OCT Avanti with Normative Database is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disc measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases.

The RTVue XR OCT Avanti with AngioVue™ software is indicated as an aid in the visualization of vascular structures of the retina and choroid.

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## Device Description

### 1. RTVue XR OCT Avanti (without AngioVue™ software module)

The RTVue XR OCT Avanti is a non-invasive diagnostic device for imaging the cornea, anterior chamber, and measurement of the retina, retinal nerve fiber layer and optic disc with micrometer range resolution as a tool and aid in the diagnosis and management of retinal disease. Imaging and measurements include but are not limited to the internal limiting membrane (ILM), the retinal nerve fiber layer (RNFL), the ganglion cell complex (GCC), the retinal pigment epithelium (RPE), the outer retinal thickness, the total retinal thickness and optic disc structures including the cup and neuroretinal rim as an aid in the diagnosis and management of retinal disease. The measurements for the ILM and RPE are height measurements relative to the RPE reference plane. The RNFL, GCC and outer retinal thickness and total retinal thickness are thickness measurements where RNFL is the thickness of the RNFL layer, the GCC is the thickness from the ILM to the inner plexiform layer (IPL), the outer retinal thickness is the thickness from the IPL to the RPE, and total retinal thickness is the thickness from the ILM to the RPE.

The RTVue XR OCT Avanti is a computer controlled ophthalmic imaging system. The device scans the patient's eye using a low coherence interferometer to measure the reflectivity of the retinal tissue. The cross sectional retinal tissue structure is composed of a sequence of A-scans. It has a traditional patient and instrument interface like most ophthalmic devices. The computer has a graphic user interface for acquiring and analyzing the image. The line-scan camera operates at approximately 70,000 A-lines per second.

The RTVue XR OCT Avanti offers three scan types: Retina, Glaucoma, and Cornea. For the cornea and anterior eye scans, a lens must be attached to the front of the device for proper scanning. This lens is called the CAM auxiliary attachment (Cornea Anterior Module). The CAM software module provides for menu selections in the graphical user interface, which are selected by the operator to label corresponding corneal landmarks instead of those of the retina.

With the normative database (NDB), the RTVue XR OCT Avanti can compare the measured data from the GCC, the RNFL, the full retinal thickness, optic disc cup and optic disc rim measurements to the normative database. The device will provide the analysis information to be used as a clinical reference to aid in the diagnosis and management of ocular diseases.

There are two device configurations available, depending on the input voltage requirements at the facility intended for installation of the device:

Model Number	Power Requirements		
	Voltage	Frequency	Current
RTVue XR 100-1	100-120 VAC	50/60 Hz	8.33 A
RTVue XR 100-2	200-240 VAC	50/60 Hz	4.38 A

## 2. RTVue XR OCT Avanti with AngioVue™ angiography software module

The RTVue XR OCT with AngioVue™ has an additional software module to aid in the visualization of vascular structures of the retina and choroid using a motion-contrast techniques without the need for intravenous dyes.

### **Summary of Technological Characteristics**

The RTVue XR OCT Avanti with AngioVue Software uses the same hardware as the previously cleared RTVue XR OCT. The RTVue XR OCT Avanti with AngioVue Software uses the previously cleared RTVue XR software with the addition of the AngioVue software module for OCT angiography scans. The AngioVue software uses motion contrast techniques to aid in the visualization of vascular structures of the retina and choroid.

The AngioVue scan performs sequential OCT cross-sectional scans to detect the motion of scattering particles such as red blood cells within the eye's vasculature. The software module also provides the ability to visualize the three-dimensional microvasculature of the retina and choroid. AngioVue image processing can employ a proprietary motion correction technology (MCT) to reduce potential artifacts caused by blinks and eye motion during scan acquisition.

### **Performance Testing**

The RTVue XR OCT device with normative database was previously verified for performance and functionality to assure conformance to the requirements for its basic intended use. Biocompatibility, electromagnetic compatibility, and electrical safety testing was conducted on the previously cleared RTVue XR OCT device. Since there were no hardware changes, these performance and safety tests were not required to be repeated.

The RTVue XR OCT Avanti with AngioVue Software has the additional OCT angiography software module. Software documentation was prepared and submitted for a "moderate" Level of Concern device in accordance with FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*. Device software was verified and validated to support the proposed indications for use according to IEC 62304:2006 *Medical device software – Software life cycle processes* and FDA's *General Principles of Software Validation; Final Guidance for Industry and FDA Staff*.

### **Risk Analysis**

The new software module was assessed to make sure all the risks were sufficiently mitigated and that no new hazards were introduced as a result of the new software features according to the intended use. Identification of the associated hazards has been performed in order to evaluate, estimate and control the associated risks in accordance with EN ISO 14971 *Application of risk analysis to medical devices*.

### **Summary of Changes**

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The new AngioVue™ OCT angiography software module can be installed on the previously cleared RTVue XR OCT device to provide a three-dimensional image of the microvasculature of the retina and choroid. The AngioVue software features include data acquisition options as well as data review reports.

Additionally, a proprietary motion correction technology (MCT) will be used in conjunction with AngioVue OCT angiography images to minimize potential artifacts caused by blinks and eye motion during scan acquisition. The MCT performs motion correction based on minimization of the overall difference between the two scan volumes acquired during OCT angiography image capture.

### **Conclusions From Data**

All testing deemed necessary was conducted and the results demonstrated that the RTVue XR OCT Avanti with AngioVue Software is as safe and as effective as the predicate device for the intended use. Testing, risk analysis and image comparison to fluorescein angiography also confirmed that no new questions of safety or effectiveness were identified. Previously submitted testing that originally supported use of the RTVue XR OCT remains sufficient and unchanged in the modified device software.

Based upon no significant differences between the proposed device and the predicate device, the RTVue XR OCT Avanti with AngioVue Software is substantially equivalent in design, features, performance, fundamental scientific technology, and is appropriate for the proposed indications for use.

In case examples of a variety of retinal diseases, RTVue XR OCT Avanti with AngioVue Software cube scans were compared with fluorescein angiography images. The images demonstrate that the RTVue XR OCT Avanti angiography in combination with OCT intensity-based information can give non-invasive three-dimensional information regarding retinal microvasculature in the retina and choroid. RTVue XR OCT Avanti angiography is not intended as a substitute for fluorescein angiography. Vascular findings on fluorescein angiography may be absent, poorly defined, or variably defined on RTVue XR OCT Avanti with AngioVue Software angiography scans. Additionally, dye leakage, staining, and pooling are not features of OCT angiography.

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