April 21, 2025

OcuSciences, Inc.
% Robert Bard
Regulatory Consultant/Attorney
HealthCare Technologies Consultants, LLC
111 S Lafayette St
No 506
South Lyon, Michigan 48178

Re: K241931
Trade/Device Name: OcuMet Beacon (OCUB100)
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: MYC
Dated: March 18, 2025
Received: March 18, 2025

Dear Robert Bard:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Y. Ng -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241913

Device Name
OcuMet Beacon

Indications for Use *(Describe)*
OcuMet Beacon is a confocal scanning ophthalmoscope indicated for infrared (IR) and autofluorescence (AF) imaging of a human retina with or without the use of a mydriatic agent.

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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OCUSCIENCES

510(k) Summary – K241931

Date of preparation:	April 18, 2025
Proprietary Name(s):	OcuMet Beacon
Manufacturer:	Kurt Riegger OcuSciences Inc. 2890 Carpenter Rd Suite 1800 Ann Arbor, M8108
Telephone **Email**	734 623-9434
Official Contact Person	Robert J Bard, JD, CQE, RAC HealthCare Technologies Consultants, LLC 111 Lafayette South Lyon, MI 48178-9998 rbard@reglaw.net +734 330 5990
Classification Name	Ophthalmoscope, AC Powered Ophthalmoscope, Laser, Scanning
Product Code:	MYC
Regulation Number:	886.1570
Common Name:	Ophthalmoscope
Panel:	Ophthalmic
Class:	II
Indications for Use:	Ocumet Beacon is a confocal scanning ophthalmoscope indicated for infrared (IR) and autofluorescence (AF) imaging of a human retina with or without the use of a mydriatic agent.

Legally marketed device (Predicate)	Predicate: EIDON FA, EIDON, EIDON AF, EIDON UWFL (K211328) Reference Device: Heidelberg Spectralis HRA (K201252 Spectralis HRA+OCT and variants)

OCUSCIENCES

Device description

Ocumet Beacon is a scanning LED based ophthalmoscope which uses infrared and blue light to obtain confocal images of the retina. Multiple retinal fields can be captured using a programmable internal fixation target. The device integrates a tablet and is provided with an external power supply. The device works with a dedicated software application and operates as a standalone unit.

Ocumet Beacon offers two different acquisition modalities:

- black and white reflectance images of the retina obtained using infrared illumination;
- black and white fluorescence images of the retina obtained using blue illumination (peak at 458 nm) and a barrier filter to select only autofluorescent emission between 520 and 540 nm.

Clinician Report Generator Software is required to open, review, analyze, and print images obtained from Ocumet Beacon. The software runs on a standalone laptop.

The total light exposure is qualified as Group 1 under ANSI Z80.36-2016

Clinician Report Generator Software is required to open, review, analyze and print a co-registered version of both the infrared and visible wavelength images obtained from Ocumet Beacon. The software runs on a standalone Windows 10 or 11 based laptop computer.

The clinical interpretation of the images acquired by Ocumet Beacon is restricted to licensed eye care practitioners. A device specific training is required for any operator to become able to use the system and certification training is available for operators who will be capturing images in a clinical trial. The interpretation and use in clinical practice is as an adjunctive modality for the clinician to optionally combine with other structural images, and functional studies.

1.1 The device

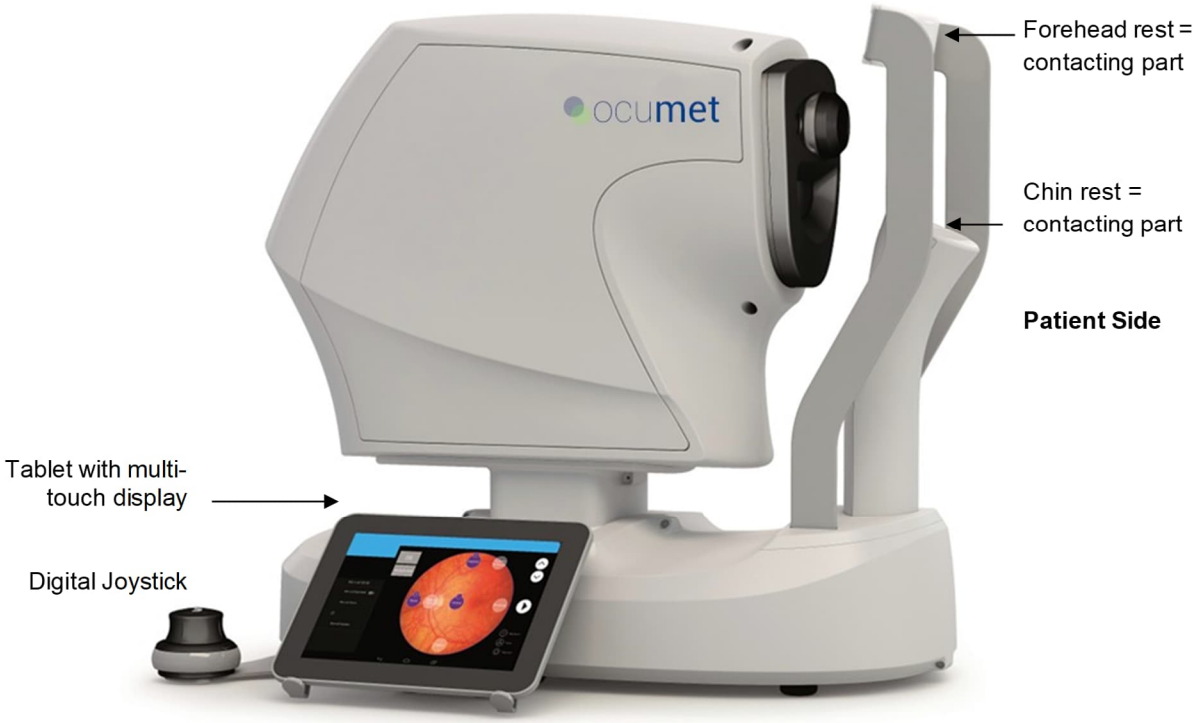

Fig. 1 – Ocumet Beacon

Fig. 2 – Detail of connectors side

The Predicate and Reference Device

This submission includes a Predicate and Reference Device

a) EIDON FA/AF (k211328) is the Predicate

The CenterVue EIDON AF is a confocal scanning ophthalmoscope indicated for color, infrared and auto-fluorescence imaging and fluorescein angiography of a human retina with or without the use of a mydriatic agent.

CenterVue EIDON is a scanning ophthalmoscope which uses white light to obtain color images of the retina, infrared light to obtain infrared-reflectance images of the retina, and blue light to obtain autofluorescence and fluorescence images.

The CenterVue EIDON is part of a family of devices, which includes three models: EIDON FA, EIDON AF, and EIDON. EIDON is the base model, which features the following imaging modalities: infrared reflectance, color and red-free. EIDON AF adds autofluorescence imaging to the base model.

b) SPECTRALIS HRA+OCT is the reference device. The SPECTRALIS is a non-contact ophthalmic diagnostic imaging device. It is intended for viewing the posterior segment of the eye, including two- and three-dimensional imaging, cross-sectional imaging (SPECTRALIS HRA+OCT and SPECTRALIS OCT), fundus photography, fluorescence imaging (fluorescein angiography, indocyanine green angiography; SPECTRALIS HRA+OCT, SPECTRALIS HRA), autofluorescence imaging (SPECTRALIS HRA+OCT, SPECTRALIS HRA and SPECTRALIS OCT with BluePeak) and to perform measurements of ocular anatomy and ocular lesions.
The Spectralis and the Beacon have similar features in their autofluorescence . The Spectralis has the

BluePeak™ autofluorescence, a non-invasive scanning laser fundus imaging modality.

the Ocumet Beacon has a non- invasive confocal scanning LED autofluorescence modality.

Substantial Equivalence Table for Ocumet Beacon and Predicate

Parameter	**EIDON FA/AF (k211328) Primary Predicate**	**Ocumet Beacon AF version 1.6** (k241931)	**Comments**
Indicated Use	The Centervue EIDON is intended for taking digital images of a human retina with or without the use of a mydriatic agent.	Ocumet Beacon is a confocal scanning ophthalmoscope indicated for infrared (IR) and autofluorescence (AF) imaging of a human retina with or without the use of a mydriatic agent.	Similar
Device type	Confocal scanning LED based ophthalmoscope	Confocal scanning LED based ophthalmoscope	Same
Field of View	60° (H) x 55° (V) captured in a single exposure 80° (H) x 75° (V) captured in a single exposure, with Ultra Widefield Lens	IR 60° (H) x 21.5° (V) AF 17° (H) x 21.5° (V)	Similar Ocumet has reduced field of view: Entire field can be viewed in multiple acquisitions
Modalities	Color, red-free, IR reflectance, autofluorescence (AF), fluorescein-angiography (FA) Blue LED	Infrared (IR) Autofluorescence (AF) Blue LED	Similar without Color fundus, red-free and FA modality Autofluorescence (AF) image from the Beacon output is black-and-white in gray scale and can be enhanced with color-coded images.
Imaging Modality- IR	Line Scanning IR 850 nm	Line Scanning IR 850 nm	Same

Parameter	EIDON FA/AF (k211328) Primary Predicate	Ocumet Beacon AF version 1.6 (k241931)	Comments
Imaging Modality- autofluorescence	Line Scanning excitation LED 440-475 nm and detection greater than 500 nm	Line Scanning excitation LED plus filter 460-475 nm and detection filter 520-540 nm	Similar excitation with Blue LED but narrower filtering in detection wavelengths for Ocumet.
Light Safety	EIDON with software version 4.0 and Ultra Widefield Lens fulfills the requirements for a group 2 determination according to ANSI Z80-36, i.e., ophthalmic instruments with potential light hazard.	Group 1 according to ANSI+Z80.36-2016 and ISO 15004-2:2007	Same
Electrical Safety EMC	Electrical safety and electromagnetic compatibility The device complies with IEC 60601-1 and IEC 60601-1-2	Electrical safety and electromagnetic compatibility The device complies with IEC 60601-1 and IEC 60601-1-2	Same
Blue light source	Blue LED	Blue LED	Similar with slightly longer blue excitation wavelength peak near 465nm Ocumet

Reference Device

Parameter	Heidelberg Spectralis HRA (K201252 Spectralis HRA+OCT and variants)	OcuMet Beacon version 1.6	Summary
Indicated Use	The SPECTRALIS is a non-contact ophthalmic diagnostic imaging device. It is intended for viewing the posterior segment of the eye, including two- and three-dimensional imaging, cross-sectional imaging (SPECTRALIS HRA+OCT and SPECTRALIS OCT), fundus photography,	Ocumet Beacon is a confocal scanning ophthalmoscope indicated for infrared (IR) and autofluorescence (AF) imaging of a human retina with or without the use of a mydriatic agent.	Similar in autofluorescence however the Ocumet does not have OCT, fundus photography,

Parameter	Heidelberg Spectralis HRA (K201252 Spectralis HRA+OCT and variants)	OcuMet Beacon version 1.6	Summary
	fluorescence imaging (fluorescein angiography, indocyanine green angiography; SPECTRALIS HRA+OCT, SPECTRALIS HRA), autofluorescence imaging (SPECTRALIS HRA+OCT, SPECTRALIS HRA and SPECTRALIS OCT with BluePeak) and to perform measurements of ocular anatomy and ocular lesions. The device is indicated as an aid in the detection and management of various ocular diseases, including age-related macular degeneration, macular edema, diabetic retinopathy, retinal and choroidal vascular diseases, glaucoma, and for viewing geographic atrophy as well as changes in the eye that result from neurodegenerative diseases. The SPECTRALIS HRA+OCT and SPECTRALIS OCT include reference databases for retinal nerve fiber layer thickness and optic nerve head neuroretinal rim parameter measurements, which are used to quantitatively compare the retinal nerve fiber layer and neuroretinal rim in the human retina to values found in normal subjects.		fluorescein angiography, indocyanine green angiography;
Electrical Safety EMC	The SPECTRALIS HRA+OCT has been tested according to IEC 60601-1 and IEC 60601-1-2 and was found to meet all requirements.	Electrical safety and electromagnetic compatibility The device complies with IEC 60601-1 and IEC 60601-1-2	Same standards
Blue Light Source	Blue Laser excitation at 488 nm	Blue LED with filter to create a 460-475 nm excitation	Similar Laser is a single nm width light source and LED with filter provides a

Parameter	Heidelberg Spectralis HRA (K201252 Spectralis HRA+OCT and variants)	OcuMet Beacon version 1.6	Summary
			similarly narrow excitation light source.
Modalities	Color, red-free, IR reflectance, autofluorescence (AF), fluorescein-angiography (FA)	Infrared (IR), Autofluorescence (AF)	Similar without Color fundus, red-free and FA images
Device type	Ophthalmoscope, Laser, Scanning ProCode: MYC The device is a combination of optical coherence tomography (OCT) with confocal scanning laser ophthalmoscopy (cSLO). The system is a laser product of Class 1 according to 21 CFR §1040.10 and complies with IEC 60825-1.	Confocal scanning LED based ophthalmoscope ProCode: MYC	Similar except light sources are minimally different as a laser vs LED with filter.

Dimensional Characteristics Comparison

Parameter	EIDON FA (**k211328**)	Heidelberg Spectralis HRA w BluePeak (K201252 Spectralis HRA+OCT and variants)	OcuMet Beacon version 1.6	Summary
Dimensions	620 x 590 x 360 mm	486 x 870 x 874 mm	620 x 590 x 360 mm	Similar
Weight	25 Kg	36 Kg	25 Kg	Similar
Voltage	12 VDC	100-240 V	12 VDC	Similar except power sources are different as a laser vs LED
Power consumption	60 W	140 VA	60 W	Similar except power sources are different as a laser vs LED

Performance Testing

The system has been tested and meets relevant standards for electrical safety, light hazard, biocompatibility and system verification and validation testing.
For electrical safety and EMI, the device complies with IEC 60601-1 and IEC 60601-1-2.
For light hazard, the device meets Group 1 light safety under ANSI+Z80.36-2016 and ISO 15004-2:2007.
The patient contact points meet all biocompatibility testing requirements.
The system was tested and passes system verification and validation testing.

Conclusion

The Ocumet Beacon is a device modification to the FDA cleared EIDON AF predicate device. The Ocumet Beacon has the same Indications for Use and the same technology as the cleared EIDON AF predicate device. Based on the Performance Testing and Comparison with the Predicate, the Ocumet Beacon is substantially equivalent to the EIDON AF and has the autofluorescence performance comparable to the Reference Device.

In summary, OcuSciences' Ocumet Beacon has the same technical features and safety profile as the EIDON AF and poses no new safety risks.. Therefore the Ocumet Beacon, is substantially equivalent to the predicate device and meets the current standards. Based on the comparison of the predicate and reference device the Ocumet Beacon is substantially equivalent.