



December 3, 2015

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

Bioptigen, Inc.
Ms. Tammy B. Carrea
Vice President, Quality and Regulatory Affairs
633 Davis Drive, Suite 480
Morrisville, North Carolina 27560

Re: K150722
Trade/Device Name: Enfocus 2300, Enfocus 4400
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: HLI, OBO
Dated: October 23, 2015
Received: October 29, 2015

Dear Ms. Carrea:

This letter corrects our substantially equivalent letter of December 12, 2015.

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 Y. Alexander -A

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)
K150722

Device Name
EnFocus

Indications for Use (Describe)

The Biotigen EnFocus™ device is intended to acquire, process, display and save depth-resolved images of ocular tissue microstructure using Spectral Domain Optical Coherence Tomography (SDOCT).

The EnFocus™ is indicated for use as an aid in the visualization of physiologic and pathologic conditions of the eye through non-contact optical imaging. It is indicated for use on patient populations from premature and neonatal infants to adult. The system is indicated for use in supine imaging, mounted to a surgical microscope, with cooperative patients or patients under anesthesia.

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 (per 21 CFR 807.92)

K150722

Date Prepared: November 24, 2015

I. SUBMITTER INFORMATION

Sponsor: Bioptigen, Inc.
Registration Number: 3006809695
Address: 633 Davis Drive, Suite 480
Morrisville, NC 27560
Phone: 919-595-1260
Contact Person: Tammy B. Carrea
VP Quality and Regulatory Affairs

II. DEVICE IDENTIFICATION

Trade or proprietary name: **EnFocus™**
Common or usual name: Optical Coherence Tomography
Classification Name: Ophthalmoscope, AC Powered
Optical Coherence Tomography
Regulation: 21 CFR 886.1570
Classification: Class II
Product Codes: HLI (Ophthalmoscope, AC-powered)
OBO (Tomography, Optical Coherence)
Classification Panel: Ophthalmic

III. PREDICATE DEVICE

Envisu™ SDOIS (Models C2200 and C2300) K120057

IV. DEVICE DESCRIPTION

The EnFocus™ is a non-contact, noninvasive ophthalmic imaging device that includes an OCT Engine, a scan head, a System Computer, an Uninterruptible Power Supply (UPS), a mobile Security Cart and the System Software. The EnFocus™ uses Spectral Domain Optical Coherence Tomography (SD-OCT) and a near infrared light source to image ocular tissue microstructures

The EnFocus is coupled to a surgical microscope for OCT imaging during ophthalmic surgical procedures. The EnFocus has been validated and found to be compatible for use with the Leica



M844 Surgical Microscope and the Insight Instruments Super View™ Wide Angle Viewing System™ for retina visualization.

The software, InVivoVue™ Version 2.6, works with the hardware and the hardware controller to offer intuitive, flexible system control for high-speed volume data acquisition and imaging.

The EnFocus™ system includes two OCT-compatible objective lenses for use with the surgical microscope: a 175mm lens and 200mm lens. The system also offers a choice of accessory masks that may be deployed in the Leica M844 filter port to manage illumination glare artifacts when necessary.

Using the EnFocus™, OCT imaging may be acquired during the surgical procedure, without stopping a procedure or repositioning the surgical microscope. The surgical microscope position is stationary relative to the surgical procedure, and the surgical view is unaltered by the scanning of the OCT beam.

V. INDICATIONS FOR USE

The Bioptigen EnFocus™ device is intended to acquire, process, display and save depth-resolved images of ocular tissue microstructure using Spectral Domain Optical Coherence Tomography (SDOCT).

The EnFocus™ is indicated for use as an aid in the visualization of physiologic and pathologic conditions of the eye through non-contact optical imaging. It is indicated for use on patient populations from premature and neonatal infants to adult. The system is indicated for use in supine imaging, mounted to a surgical microscope, with cooperative patients or patients under anesthesia.

VI. SUBSTANTIAL EQUIVALENCE

Like its predicate, the EnFocus™ is a non-contact, non-invasive ophthalmic imaging device that can be used to view ocular tissue physiology and pathology through the interaction of light with the optical scattering properties of structures of the eye using SDOCT and a Class 1 near-infrared laser light source to capture depth-resolved images of ocular tissue microstructure. Both devices utilize SDOCT, include a scan head, a System Computer, an Uninterruptible Power Supply (UPS), a mobile Security Cart and the InVivoVue System Software. The design modifications represented by the subject EnFocus are, as follows:

Scan Head

The scan head is mounted to the microscope's optical carrier using a mounting bracket that is bolt-secured to the carrier's accessory plate and shares an objective lens with the microscope.



Focus and Zoom Control

The predicate device utilizes a manual system for focusing the OCT beam. Focus of the predicate device is manually achieved by mechanical displacement of lenses in the system objective lens, similar to manual operation of a SLR camera lens.

The subject device provides an electromechanical system for focusing the OCT beam and for changing the numerical aperture of the OCT beam. Focus and numerical aperture are user-controlled via an input beam zoom setting that is accessed through the software user interface.

Retina Viewing Lens

Retina viewing with the predicate device is accomplished using the General Retina Lens, one of multiple lenses supplied by Bioptigen with the Envisu SDOIS system. Retina viewing with the EnFocus is accomplished using a commercially available Fundus (Retina) Viewing Lens.

Spectrometer

The predicate device is available with one of two spectrometers (2200 or 2300) and one of two internal light sources (HR or VHR). The EnFocus device is available in two models: EnFocus 2300 includes the 2300 spectrometer of the predicate and the VHR superluminescent diode (SLD) light source of the predicate. EnFocus 4400 includes a 4400 spectrometer and utilizes an HR superluminescent light source equivalent to the HR source available with the predicate.

Engine Control System

The predicate system relied on manual control functionality of reference arm path length, reference arm attenuation level and polarization balance through mechanical linkages in the system. The EnFocus replaces these mechanical linkages with a motor-driven electromechanical system that can be controlled through a menu on the front panel of the EnFocus engine or through the software user interface.

Software User Interface and Function

No changes have been made to the predicate's underlying method of image acquisition, signal processing or display technology.

Software modifications include migration to the Microsoft 7 64-bit Operating System and simplification of both user interface and workflow. Examples of these simplifications include Office 2010 and 2013 support for reports, enabling simultaneous exporting of multiple exams, rearranging the user interface layout to follow standard workflows while reducing the steps to begin a new patient exam and associating an exam with patient demographic data.

Two new user interface features have been added including a configuration drop down menu and a prominently displayed "Quick Start" grid. The drop down menu simplifies switching



between system configurations for anterior and posterior imaging without requiring restarting InVivoVue software.

Any technological differences between the EnFocus and Envisu devices have been mitigated via bench testing or clinical testing.

VII. NON-CLINICAL PERFORMANCE DATA

Medical Electrical Safety Testing

Electrical safety and EMI/EMC testing were conducted on the EnFocus and demonstrate the system complies with the IEC 60601-1 and IEC 60601-1-2 standards, 3rd edition. Testing included review of the software, risk management file, and usability file.

Optical Safety and Emissions

IEC 60825-1 Class 1 laser product safety testing and ISO 15004-2 Group 2 light hazard test results together confirm the system to be eye safe when used as labeled.

Software Verification and Validation Testing

Software testing was validated and documentation provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and in accordance with the software lifecycle requirements of ISO 62304.

Key Performance Attributes

Optical performance testing was conducted in accordance with established key performance attributes. All testing demonstrated compliance with applicable product requirements.

Surgical Microscope Compatibility

The EnFocus was connected to the microscope and the two EnFocus device models were evaluated for compatibility with the microscope. Compatibility was assessed by evaluating the ability of the microscope and EnFocus to work independently and by ensuring that the EnFocus did not result in any form of interference with the microscope that could impact surgical performance. The microscope and EnFocus were tested together for optical radiation safety to ISO 15004-2, mechanical connectivity, mechanical stability, ergonomics and working distance, and general safety. Microscope properties were evaluated for optical performance including illumination field of view, illumination uniformity, optical distortion, and glare. Installation and removal, including draping, were evaluated. The surgical microscope labeling was evaluated to ensure that the microscope was not contraindicated for pediatric use. Illumination field of view and uniformity were evaluated with and without the accessory glare masks installed. All tests for compatibility passed acceptance criteria.



Fundus Viewing System Compatibility

The optical resolution of the surgical microscope with the fundus viewing system installed was evaluated with and without the EnFocus installed. Both of the two EnFocus objectives were evaluated at the maximum and minimum microscope magnifications. Evaluations demonstrated equivalent fundus imaging optical resolution with and without the EnFocus device installed.

Performance Specifications

Attribute	Predicate Envisu Device K120057 Models 2200/2300	Proposed EnFocus Device K150722 Models 2300/4400
Indications for Use	<p>Bioptigen SDOIS is intended to acquire, process, display and save depth-resolved images of ocular tissue microstructure using Spectral Domain Optical Coherence Tomography (SDOCT). The Envisu SDOIS is indicated for use as an aid in the diagnosis of physiological and pathologic conditions of the eye through non-contact optical imaging. Imaging of the various tissues of the eye is supported through the use of interchangeable lenses. It is indicated for use on patient population from premature and neonatal infants to adult, and is suitable for patients ambulatory or confined. The system is indicated for use in upright or supine imaging, handheld or mounted, and is suited for imaging patients under anesthesia.</p>	<p>The Bioptigen EnFocus™ device is intended to acquire, process, display and save depth-resolved images of ocular tissue microstructure using Spectral Domain Optical Coherence Tomography (SDOCT). The EnFocus™ is indicated for use as an aid in the visualization of physiologic and pathologic conditions of the eye through non-contact optical imaging. It is indicated for use on patient populations from premature and neonatal infants to adult. The system is indicated for use in supine imaging, mounted to a surgical microscope, with cooperative patients or patients under anesthesia.</p>
Regulation Number	21 CFR 886.1570	Same
Class	II	Same
Method of Operation	Spectral Domain Optical Coherence Tomography	Same
Light Source	SLD (Superluminescent diode)	Same
Scanner Type	Galvanometric mirror pair	Same
Optical Power	≤ 750 μW	Same
Resolution, Lateral	<p>Retina: 20 μm in tissue</p> <p>Anterior: 9, 12, 25 μm in tissue</p>	<p>< 31.0 μm (175 mm Obj., low NA)</p> <p>< 15.1 μm (175 mm Obj., high NA)</p> <p>< 35.4 μm (200 mm Obj., low NA)</p> <p>< 17.3 μm (200 mm Obj., high NA)</p>

Resolution, Axial		HR: $\leq 6 \mu\text{m}$ in tissue VHR: $<4 \mu\text{m}$ in tissue	HR: $\leq 9 \mu\text{m}$ VHR: $\leq 4 \mu\text{m}$
Field of View (air/tissue) (aka depth range)		Model C2200: 2.3/1.7 mm Model C2300: 3.4/2.5 mm	Model 2300: 3.4/2.5 mm Model 4400: 15.3/11.1 mm
Scan Pixels	Axial	Model C2200: 1024 Model C2300: 1024	Model 2300: 1024 Model 4400: 2048 pixels
	Lateral	User selectable A-scans/B-scan: 5000 maximum	User selectable A-scans/B-scan: 2000 maximum
		Maximum: 150,000 total A-scans	Maximum A-scans/volume Model 2300: $\geq 1,000,000$ Model 4400: $\geq 500,000$
Scan Rate		$\geq 32,000$ A-scans/s	Model 2300: $\geq 32,000$ A-scans/s / Model 4400: $\geq 18,000$ A-scans/sec
Scan Patterns		Line, rectangular volume, circle, concentric rings, radial lines	Same
Calipers		Manual placement of on-screen calipers	Same
Doppler		Qualitative blood flow visualization with color Doppler OCT	Same
Software		InVivoVue 1.4	InVivoVue 2.6

VIII. CLINICAL DATA

Clinical data were collected in an IRB approved study to support the indications for use statement for the EnFocus 2300 and EnFocus 4400 systems and to demonstrate substantial equivalence as compared to the predicate Envisu 2300 device with regard to the ability to:

- a) visualize ocular physiology of the anterior and posterior segments of the eye
- b) visualize vascular blood flow in the retina with Doppler OCT
- c) perform measurements of ocular features using manual placement of on-screen calipers.

The study evaluated 24 eyes of twelve adult subjects. Subjects were imaged in an office setting beneath a Leica M844 microscope, without mydriasis. Images were coded and randomized. Following collection of images, three ophthalmic graders independently reviewed the images and documented evaluations

Ocular Physiology and Presence of Doppler Flow

Three ophthalmic graders evaluated four volumetric images acquired of each subject eye and identified the presence or absence of physiologic features in a binary test of agreement. The ability to visualize and identify the physiologic structures are presented in the following table:

ID	Feature	ENF2300		ENF4400	
		N	Percent Agreement with Predicate	N	Percent Agreement with Predicate
Q2	Inner limiting membrane	71	81.7%	72	80.6%
Q3	Parafov. nerve fiber layer	70	100.0%	72	100.0%
Q4	Inner nuclear layer	71	100.0%	72	100.0%
Q5	Outer plexiform layer	71	100.0%	72	100.0%
Q6	Ext. limiting membrane	71	100.0%	72	100.0%
Q7	IS/OS Ellipsoids	71	100.0%	72	100.0%
Q8	End Tips Photoreceptor	71	98.6%	72	94.4%
Q9	Retina pigment epithelium	71	100.0%	72	100.0%
Q10	Choriocapillaris	71	100.0%	71	100.0%
Q11	Chorioscleral interface	72	66.7%	72	62.5%
Q14	Cornea epithelium	70	100.0%	71	100.0%
Q15	Bowman's layer	70	94.3%	71	98.6%
Q16	Cornea endothelium	70	98.6%	71	98.6%
Q19	Scleral corneal junction	72	98.6%	72	97.2%
Q20	Schlemm's canal	70	60.0%	71	57.7%
Q21	Iridocorneal angle	71	81.7%	72	63.9%
Q22	Doppler flow, superior	72	93.1%	72	95.8%
Q23	Doppler flow, central	72	88.9%	72	88.9%
Q24	Doppler flow, inferior	72	95.8%	72	95.8%

Caliper Measurements

Graders were asked to use InVivoVue calipers to measure a series of features in the same images. The images were presented as acquired, without magnification, or image processing or image enhancement. The caliper measurements from images acquired with each of the EnFocus 2300 and EnFocus 4400 were analyzed for agreement with images acquired with the predicate Envisu 2300. Agreement was tested against a target equivalence margin of +/- 15 um (0.015 mm) at the 95% confidence level. Results are tabulated in the following table:

New Device	Measurement	N	Mean Difference (Predicate - New Device (mm))	SD	Lower 95% CI	Upper 95% CI	95% CI Meets Equivalence Margin? (+/- 0.015 mm)
ENF2300	Parafoveal peak, inferior	24	0.0064	0.0047	0.0045	0.0084	Y
	Parafoveal peak, superior	24	0.0036	0.0056	0.0013	0.0060	Y
	Fovea	24	0.0013	0.0064	-0.0014	0.0040	Y
	Nerve Fiber Layer, 1mm from parafoveal peak	24	0.0026	0.0047	0.0006	0.0046	Y
	Cornea	24	0.0085	0.0063	0.0059	0.0112	Y
	Cornea Epithelium	24	0.0044	0.0022	0.0035	0.0053	Y
ENF4400	Parafoveal peak, inferior	24	-0.0009	0.0045	-0.0028	0.0010	Y
	Parafoveal peak, superior	24	-0.0026	0.0054	-0.0049	-0.0004	Y
	Fovea	24	-0.0051	0.0085	-0.0087	-0.0015	Y
	Nerve Fiber Layer, 1mm from parafoveal peak	24	-0.0025	0.0049	-0.0045	-0.0004	Y
	Cornea	24	-0.0028	0.0081	-0.0062	0.0006	Y
	Cornea Epithelium	24	0.0020	0.0030	0.0008	0.0033	Y



The linearity in agreement between measures across the range of measurements (20 um to 630 um) was also evaluated. The best linear fits ($\text{Device2} = A \cdot \text{Device1} + B$) and correlation coefficient R^2 are presented in the following table.

Accuracy		A (%)	B (μm)	R2 (%)
Pooled Graders	ENF23=f(Pred)	99.0%	-2.0	99.8%
	ENF44=f(Pred)	100.2%	1.4	99.8%
	ENF44=f(ENF23)	101.2%	3.5	99.8%

IX. CONCLUSION

The EnFocus™ device shares the same fundamental technology as the predicate Envisu SDOIS and has a similar intended use.

The conclusion drawn from the test data is that the EnFocus device is as safe and effective as the predicate device and performs similarly to the predicate device. Any differences in technology have been tested and verified and do not raise any new issues of safety and effectiveness.