



Food and Drug Administration  
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December 9, 2016

Bioptigen, Inc.  
Ravi Kommineni  
Director of Quality and Regulatory Affairs  
633 Davis Drive, Suite 480  
Morrisville, NC 27560

Re: K162783  
Trade/Device Name: EnFocus 2300, EnFocus 4400  
Regulation Number: 21 CFR 886.1570  
Regulation Name: Ophthalmoscope  
Regulatory Class: Class II  
Product Code: OBO  
Dated: November 16, 2016  
Received: November 17, 2016

Dear Mr. Kommineni:

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,

  
**Denise L. Hampton -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

## Indications for Use

510(k) Number (if known)

Device Name

EnFocus™ (EnFocus 2300, EnFocus 4400)

Indications for Use (Describe)

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.

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.

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## **510(k) Summary**

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safety Medical Devices Act of 1990 (SMDA 1990) and 21 CFR Part 807.92

### **I. General Information**

**Manufacturer:** Bioptigen, Inc.  
A Leica Microsystems Company  
633 Davis Drive, Suite 480  
Morrisville, NC 27560

**Contact Person:** Ravi Kommineni  
Director for Quality and Regulatory Affairs  
Bioptigen, Inc.  
Phone: 919-348-6439  
Email: ravi.kommineni@leica-microsystems.com

**Date Prepared:** 12/5/2016

### **II. Device Information**

**Trade Name:** EnFocus 2300, EnFocus 4400  
**Model Number(s):** 2300 (70-10091)  
4400 (70-10094)  
**Common Name:** Spectral Domain Optical Coherence Tomography  
**Classification Name:** Tomography, Optical Coherence  
**Regulation Number:** 21 CFR § 886.1570  
**Product Code:** OBO  
**Classification Panel:** Ophthalmology  
**Class:** II

### **III. Predicate Device**

EnFocus (EnFocus 2300, EnFocus 4400) - K150722



#### **IV. Purpose of Special 510(k)**

The purpose of the special 510(k) submission is to gain clearance for the changes made to the EnFocus™ (K150722) cleared device. The EnFocus™ optical and computing subsystems are now repackaged into a single enclosure for improved manufacturing and servicing logistics. The associated hardware and software changes do not affect the intended use, functionality of the system nor alter the principle of operation of the EnFocus™ device.

#### **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. Device Description**

The EnFocus™ is a non-contact, noninvasive ophthalmic imaging device that includes an OCT engine, a scan head and a system computer with 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 software, InVivoVue™, works with the hardware and the 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 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.



## VII. Substantial Equivalence

The modified EnFocus™ device has the same intended use, indications for use, technological characteristics and principle of operation as the cleared EnFocus™ device (K150722) to which it is a modification.

| Category                                                  | Predicate (EnFocus™ - K150722)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Subject (Modified EnFocus™) |
|-----------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| Indications for Use                                       | <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).</p> <p>The EnFocus™ is indicated for use as an aid in the visualization of physiologic and pathologic conditions of the eye through noncontact 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> | Same as predicate           |
| Target Population                                         | <ul style="list-style-type: none"> <li>Premature and neonatal infants to adult</li> <li>Supine</li> <li>Cooperative patients or patients under anesthesia</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                               | Same as predicate           |
| Anatomical Sites                                          | Anterior and Posterior Segment of Eye                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Same as predicate           |
| Method of Operation                                       | SD-OCT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Same as predicate           |
| Principle of Operation                                    | OCT dichroically coupled into collimated space of common main objective surgical microscope.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Same as predicate           |
| Energy Used and/or Delivered                              | Near Infrared Optical Emissions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Same as predicate           |
| Light Source                                              | 800 nm band SLD:<br>High Resolution (HR)<br>Very High Resolution (VHR)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Same as predicate           |
| Light Source Classification                               | Class 1 Laser Product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Same as predicate           |
| Optical Power                                             | ≤ 750 μW                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Same as predicate           |
| <b>PERFORMANCE</b>                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                             |
| Resolution, Lateral                                       | <p>&lt; 31.0 μm (175 mm Obj., low NA)</p> <p>&lt; 15.1 μm (175 mm Obj., high NA)</p> <p>&lt; 35.4 μm (200 mm Obj., low NA)</p> <p>&lt; 17.3 μm (200 mm Obj., high NA)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                          | Same as predicate           |
| Field of View, Lateral                                    | ≥ 20 mm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Same as predicate           |
| Resolution, Axial                                         | <p>Model 2300 VHR: &lt; 4 μm in tissue</p> <p>Model 4400: ≤ 9 μm in tissue</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Same as predicate           |
| Field of View, Longitudinal (Depth Range) (in tissue/air) | <p>Model 2300: 2.5 / 3.4 mm</p> <p>Model 4400: 11.1 / 15.3 mm</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Same as predicate           |



| Category                | Predicate (EnFocus™ - K150722)                                                                                                                                   | Subject (Modified EnFocus™)                            |
|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|
| Scanner Type            | Galvanometric mirror pair                                                                                                                                        | Same as predicate                                      |
| Scan Patterns Available | Line, rectangular volume, circle, concentric rings (annular volume), radial lines (radial volume)                                                                | Same as predicate                                      |
| Scan Pixels             | Axial (depth) :<br>Model 2300: 1024<br>Model 4400: 2048<br>Lateral: User Selectable<br>Maximum A-scans / B-scan: 2000<br>Maximum total A-scans/volume: 1,000,000 | Same as predicate                                      |
| Scan Rate               | Model 2300: 32,000 A-scans/sec<br>Model 4400: 18,000 A-scans/sec                                                                                                 | Same as predicate                                      |
| <b>DIMENSIONS</b>       |                                                                                                                                                                  |                                                        |
| System Footprint        | Mobile Cart: 24" x 22" x 37.5"                                                                                                                                   | Same as predicate                                      |
| Subsystem Dimensions    | Computer: 13" (w), 15.5" (l), 5.75" (h)<br>Interface Box: 13" (w), 15.5" (l), 5.75" (h)<br>OCT Engine: 17.75" (w), 17" (l), 7.5" (h)                             | Integrated Chassis:<br>19" (w) x 10.5" (l) x 8.25" (h) |
| Scanner                 | Scan head: 3.2" (h) x 3.2" (od)                                                                                                                                  | Same as predicate                                      |
| Dimensions              | Relay Arm: 10.9" (l) x 1.7" (od) Scanner Assembly: 2.2" (l) x 5.5" (w) x 8.0" (h)<br>Mounting Adapter: 2.2" (l) x 2.8" (w) x 1.8" (h)                            | Same as predicate                                      |
| Scanner Ergonomics      | Surgical Microscope Mounted                                                                                                                                      | Same as predicate                                      |
| <b>SOFTWARE</b>         |                                                                                                                                                                  |                                                        |
| Software                | InVivoVue™ (IVV) 2.6                                                                                                                                             | InVivoVue™ (IVV) 2.10                                  |
| Scan Setting Procedures | Protocol Pre-Sets, Scan Pre-Sets, Custom Scan definitions                                                                                                        | Same as predicate                                      |
| Measurements            | Manual placement of on-screen calipers                                                                                                                           | Same as predicate                                      |
| Doppler                 | Qualitative blood flow visualization with color Doppler OCT                                                                                                      | Same as predicate                                      |

## VIII. Performance

The modified EnFocus™ device is in compliance with the following recognized consensus standards:

| Standard          | Version                   | Title                                                                                                                                                  |
|-------------------|---------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| AAMI/ANSI 60601-1 | 2005/(R)2012              | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance                                                 |
| IEC 60601-1-2     | Edition 4.0 2014-02       | Medical electrical equipment – Part 1-2: General requirements for safety – Collateral Standard: Electromagnetic compatibility – Requirements and tests |
| ISO 62304         | 2015                      | Medical device software - Software life-cycle processes                                                                                                |
| ISO 14971         | Second Edition 2007-03-01 | Medical Devices – Application of Risk Management to Medical Device                                                                                     |
| IEC 60825-1       | Edition 2.0 2007-03       | Safety of laser products – Part 1: Equipment classification and requirements                                                                           |
| ISO 15004-2       | 2007                      | Ophthalmic Instruments - Fundamental Requirements And Test Methods Part 2: Light Hazard Protection                                                     |



## **IX. Non-Clinical Testing**

### **Safety**

Electrical safety and EMC testing were conducted on the modified EnFocus™ device and demonstrate that the system complies with the IEC 60601-1 and IEC 60601-1-2 recognized standards.

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.

### **Performance**

Optical performance testing demonstrates that the modified EnFocus™ maintains optical performance attributes equivalent to the original device.

Image quality testing validates that the OCT image quality of the modified EnFocus™ device is statistically equivalent to the original device.

Video compatibility testing confirms that the modified EnFocus™ hardware remains capable of displaying digital video inputs to primary and secondary monitors.

Fundus viewing system testing validates that the modified EnFocus™ is compatible with qualified fundus viewing systems.

### **Software**

InVivoVue™ software was verified and validated in accordance with the software lifecycle requirements of ISO 62304.

## **X. Clinical Testing**

No clinical information is included in this submission.

## **XI. Conclusion**

The results of verification and validation demonstrate that the modified device is as safe and effective as the predicate device and does not introduce new issues of safety and effectiveness. Therefore, the modified EnFocus™ is substantially equivalent to its cleared predicate device, EnFocus™ (K150722).