



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

July 15, 2015

Lightlab Imaging, Inc.
Erdie De Peralta
Regulatory Affairs Director
4 Robbins Road
Westford, Massachusetts 01886

Re: K150878
Trade/Device Name: ILUMIEN OPTIS
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ
Dated: June 4, 2015
Received: June 9, 2015

Dear Erdie De Peralta:

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

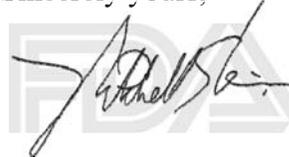
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, light gray watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE

510(k) Number (if known):

Device Name: ILUMIEN OPTIS

The ILUMIEN OPTIS with Dragonfly DUO or Dragonfly OPTIS Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The Dragonfly DUO or Dragonfly OPTIS Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The Dragonfly DUO or Dragonfly OPTIS Imaging Catheter is not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure.

The ILUMIEN OPTIS will further acquire radio frequency signal outputs from both a distal intracoronary pressure transducer and a proximal aortic pressure transducer to determine the physiological parameter, Fractional Flow Reserve (FFR). The physician may use the FFR parameter, along with knowledge of patient history, medical expertise and clinical judgment to determine if therapeutic intervention is indicated.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5. 510(K) SUMMARY

for the LightLab Imaging, Inc. ILUMIEN™ OPTIS™

(per 21CFR 807.92)

1. SUBMITTER/510(K) HOLDER

LightLab Imaging, Inc.
4 Robbins Road
Westford, MA 01886

Contact Person: Erdie de Peralta
Telephone: 978-577-3481

Date Prepared: 3/31/15

2. DEVICE NAME

Proprietary Name: ILUMIEN OPTIS
Common/Usual Name: Ultrasonic pulsed echo imaging system
Classification Name: Ultrasonic pulsed echo imaging system
Regulation number 21 CFR 892.1560
Product Code NQQ

3. PREDICATE DEVICE

- ILUMIEN OPTIS with Dragonfly OPTIS Imaging Catheter manufactured by LightLab Imaging, Inc. K141453

4. DEVICE DESCRIPTION

The ILUMIEN OPTIS is a cart-mounted computer and Imaging Engine (or optical engine) placed inside an ergonomically designed mobile cart with the cable underground. It also includes the Drive-motor and Optical Coupler (DOC), which provides the interconnection between the ILUMIEN OPTIS System and the Dragonfly Catheter. The cart is equipped with two display monitors (one for the console operator, and the other for the physician), as well as a keyboard and mouse. The cart also contains an isolation transformer for electrical safety.

The cart includes two USB mounted FFR receivers which provide wireless reception of distal intracoronary and aortic pressure signals originating at the PressureWire® Aeris and the aortic pressure transducer (AIU). These signals are used to calculate and display the patient's Fractional Flow Reserve (FFR) on the system monitor.

5. INTENDED USE

The ILUMIEN OPTIS with Dragonfly DUO or Dragonfly OPTIS Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The Dragonfly DUO or Dragonfly OPTIS Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The Dragonfly DUO or Dragonfly OPTIS Imaging Catheter is not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure.

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6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The ILUMIEN OPTIS is equivalent to the predicate device in terms of hardware and firmware components. They both contain a DOC which provides the interconnection between the ILUMIEN OPTIS and the optical imaging catheters that emit near-infrared light to produce high-resolution real-time images. This process is accomplished for both the ILUMIEN OPTIS and the predicate device through a graphical user interface (GUI) and software control to obtain Optical Coherence Tomography (OCT) imaging modality and fractional flow reserve (FFR) measurements.

The ILUMIEN OPTIS represents an upgrade to the predicate device in terms of performance through a modified engine design and contains identical OCT imaging and hardware equipment specifications. The software has been upgraded to revision E.2 to accommodate FDML laser support.

7. PERFORMANCE TESTING

The ILUMIEN OPTIS has been tested and is in compliance with IEC 62304:2006 Medical device software -- Software life cycle processes, IEC 60601-1:2005+CORR. 1(2006) + CORR. 2(2007)-Part 1: General requirements for basic safety and essential performance, IEC 60825-1:2nd Ed. 2007 Part 1: Equipment classification and requirements, 21 CFR 1040.10 Performance Standards for Light Emitting Products, sections b5 and b15 and IEC 60601-1-2 Ed.3 Electromagnetic emissions and immunity requirements for medical electric equipment-Group 1 Equipment, Class A for non-life supporting equipment.

In addition to the electrical safety testing performed, software verification and validation was conducted to FDA regulations, standards and guidance document requirements. The results of this testing conclude the software has met these requirements. Design verification and validation was also performed as a part of bench testing on the ILUMIEN OPTIS in compliance with internal design control procedures which included engine hardware design verification and OCT Imaging Parameter testing. The results of this testing concludes the ILUMIEN OPTIS is determined to be safe and effective and is substantially equivalent to the ILUMIEN OPTIS predicate device.