



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 29, 2015

LightLab Imaging, Inc.
Padmini Suravaram
Regulatory Affairs Specialist
4 Robbins Road
Westford, MA 01866

Re: K152120

Trade/Device Name: OPTIS Mobile System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ
Dated: October 7, 2015
Received: October 8, 2015

Dear Padmini Suravaram:

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 faint, light-colored 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

Indications for Use

510(k) Number (if known)
K152120

Device Name
OPTIS™ Mobile System

Indications for Use (Describe)

The OPTIS™ Mobile System 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 OPTIS™ Mobile System 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.

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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5. 510(K) SUMMARY

**for the LightLab Imaging, Inc.
OPTIS™ Mobile System**

(per 21CFR 807.92)

1. SUBMITTER/510(K) HOLDER

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

Contact Person: Padmini Suravaram
Telephone: 978-577-3473

Date Prepared: 10/06/2015

2. DEVICE NAME

Proprietary Name: OPTIS Mobile System
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 manufactured by LightLab Imaging, Inc. K150878
- OPTIS Integrated System manufactured by LightLab Imaging, Inc. K151286

4. DEVICE DESCRIPTION

The OPTIS Mobile System is a cart-mounted computer and Imaging Engine (or optical engine) placed inside an ergonomically designed mobile cart with the cable underground. It includes the Drive-motor and Optical Coupler (DOC), which provides the interconnection between the OPTIS Mobile 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.

The OPTIS Mobile System is comprised of the following main components:

- A rapidly scanning laser engine
- A host computer with embedded application software
- A drive-motor and optical coupler (DOC) which connects to the imaging catheter
- A mobile console with monitors, keyboard and mouse housing laser engine and host computer, and connected to the DOC.
- An imaging catheter
- An optional Tableside Controller (TSC)
- Video interfaces for interaction with the boom monitor and angiography system

The function of the Tableside Controller (TSC) is to provide tableside system control to the Physician. The TSC communicates with the console via wireless configuration or an optional wired configuration.

The OPTIS Mobile System can perform both OCT and FFR procedures, and is compatible with Dragonfly OPTIS, DUO and JP catheters and the PressureWire Aeris. The OPTIS Mobile system provides the ability to incorporate the angiography images into the GUI, which allows users to visualize the position of OCT image data on angiography images, tightening the linkage between anatomical assessment with OCT and subsequent therapeutic actions.

5. INTENDED USE

The OPTIS™ Mobile System 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 OPTIS™ Mobile System 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.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The OPTIS Mobile System is equivalent to the ILUMIEN OPTIS predicate device in terms of hardware and firmware components. They both contain a DOC which provides the interconnection between the OPTIS Mobile System and the optical imaging catheters that emit near-infrared light to produce high-resolution real-time images. This process is accomplished for both the OPTIS Mobile System 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 Angio Co-Registration and the Tableside Controller that are introduced in the OPTIS Mobile System are equivalent to the OPTIS Integrated System predicate device.

The OPTIS Mobile System represents an upgrade to the ILUMIEN OPTIS predicate device in terms of:

1. The software upgrade from E.2 to E.3 to enable Angio Co-Registration, support for wireless connectivity of Tableside Controller & added support for multiple room based configurations enabling the use of FFR, ACR and Tableside Controller in multiple labs.
2. Providing necessary hardware to support Angio Co-Registration feature. The PC of the predicate device will be replaced by a new PC which will include a new video frame grabber to capture video signals from Angiography X- Ray System.
3. A new Rear I/O Panel. The I/O Panel of the predicate device will be replaced with a new I/O Panel to allow for Angio Video connection and Bluetooth interface to the Tableside

Controller. The software has been upgraded to revision E.3 to accommodate Angio Co-Registration tool and Tableside Controller.

4. An optional Tableside Controller

7. PERFORMANCE TESTING

The OPTIS Mobile System 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)+ AM1 (2012)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, 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, IEC 62366: 2007 (First Edition) + A1: 2014, Application of usability engineering to medical devices, IEC 60601-1-6: 2010+ A1:2013 Medical electrical equipment- Part 1-6: General requirements for basic safety and essential performance, IEC 60601-2-18: 2009 Medical electrical equipment- Part 2: Particular requirements for the basic safety and essential performance of endoscopic 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 on the OPTIS Mobile System in compliance with internal design control procedures which included OCT parameter and hardware testing. The results of this testing concludes the OPTIS Mobile System is determined to be safe and effective and is substantially equivalent to the ILUMIEN OPTIS predicate device.