



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 5, 2015

Lightlab Imaging, Inc.
% Erdie De Peralta
Regulatory Director
Lightlab Imaging,inc.
4 Robbins Road
Westford, Massachusetts 01866

Re: K151286

Trade/Device Name: OPTIS Integrated System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ
Dated: May 12, 2015
Received: May 14, 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,

Bram D. Zuckerman -S

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): K151286

Device Name: OPTIS Integrated System

Indications for Use:

The OPTIS Integrated 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 Integrated 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.

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. OPTIS Integrated System (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: 5th August 2015

2. DEVICE NAME

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

3. PREDICATE DEVICE

- OPTIS Integrated System, Dragonfly OPTIS Imaging Catheter manufactured by LightLab Imaging, Inc.K141769

4. DEVICE DESCRIPTION

The OPTIS Integrated System performs optical coherence topography (OCT) and fractional flow reserve (FFR) procedures and provides images of the coronary arteries in patients who are candidates for transluminal interventional procedures. The device utilizes fiber-optic technology to emit near infrared light and receive light reflected from coronary tissue in order to produce high resolution, real time images. The imaging engine generates wavelength scanning light, which is guided to the DOC and the catheter. The reflection is collected and sent back to the engine. The engine processes the optical signal and converts it to electrical signal, which is then fed into the Host PC. The software application processes the signal and generates OCT images. The device is compatible with Dragonfly OPTIS, Dragonfly Duo and

PressureWire Aeris.

The OPTIS Integrated System configuration has the following components integrated into a single catheterization lab.

Component	Location
Laser and Engine	Contained within the system cabinet (M5a)
PC Embedded Software	Contained within the system cabinet
DOC	Located on the table side, connected directly to the DOC Holster
Monitor Keyboard Video Mouse	Located in the control room
System Cabinet	Located within the control room or technical closet
Remoting Cable	The cable connects the DOC Holster to the system cabinet
DOC Holster	Located table side
Tableside Controller	Located table side

The OPTIS Integrated System Mobile Workstation (MWS) is an accessory for the OPTIS Integrated System. The MWS is a mobile terminal that mirrors the functionality of the control room monitor, keyboard and mouse that is part of the OPTIS Integrated System. The Control room monitor, keyboard and mouse of OPTIS Integrated System is a desktop setup located in the control room for operating system controls.

The MWS consists of two major subassemblies:

- MWS console is comprised of a cart, keyboard, mouse, monitor, wireless Keyboard/Video/Mouse (KVM) receiver, cabling, branding labels and compliance label.
- MWS transmitter is comprised of a wireless KVM transmitter, video splitter, power supplies and cabling. All items are shipped together in a single carton.

5. INTENDED USE

The OPTIS Integrated 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 Integrated 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

OPTIS Integrated System Mobile Workstation

The OPTIS Integrated System with Mobile Workstation accessory is equivalent to the OPTIS Integrated System predicate device in that both devices perform optical coherence tomography (OCT) and fractional flow reserve (FFR) procedures and provide images of the coronary arteries in patients who are candidates for transluminal interventional procedures. Both devices utilize fiber-optic technology to emit near infrared light and receive light reflected from coronary tissue in order to produce high resolution, real time images. The imaging engine in both devices generates wavelength scanning light, which is guided to the Digital Optical Coupler (DOC) and the catheter. The reflection is collected and sent back to the engine. The engine processes the optical signal and converts it to electrical signal, which is then fed into the Host PC. The software application processes the signal and generates OCT images. Both devices are compatible with Dragonfly Duo and Dragonfly OPTIS imaging catheters, in addition to the PressureWire Aeris.

The Mobile Workstation accessory has been added to the OPTIS Integrated System predicate device as an option to the OPTIS Integrated System providing an additional control point to input patient demographics and to control the OCT procedure, when needed, from anywhere in the procedure room outside the sterile field. The Mobile Workstation will communicate with the OPTIS Integrated System via a wireless communication interface capable of supporting video signal transmission and a USB keyboard and mouse interface. The Mobile Workstation functionality can be broken into two major functional blocks. The transmitter connects to the System Cabinet, and the Mobile Station itself which will be powered via AC mains and will otherwise be free of physical connections to the OPTIS Integrated System.

7. PERFORMANCE TESTING

The OPTIS Integrated System Mobile Workstation has been tested and is in compliance with IEC 60601-1:2005 + A1: 2012 Medical electrical equipment – Part 1: General requirements

for basic safety and essential performance, IEC 60601-1-6:2010 + A1: 2013 Medical electrical equipment – Part 1-6: General requirements for safety - Collateral Standard: Usability, IEC 60601-2-18:2009 Medical electrical equipment - Part 2: Particular requirements for the basic safety and essential performance of endoscopic equipment, and IEC 60601-1-2 Ed. 3, Electromagnetic emissions and immunity requirements for medical electrical equipment – Group 1 Equipment, Class A for non-life supporting equipment.

In addition to the Electrical Safety Testing performed, Hardware Design Verification, System Level Design Verification and Transport & Storage Conditions Verification was conducted to FDA regulations, standards, guidance document requirements and internal design control procedures. The results of this testing conclude the OPTIS Integrated System and Mobile Workstation have met these requirements. The Design Verification activities demonstrate that OPTIS Integrated System and the Mobile Workstation comply with the defined design and performance specifications. The addition of Mobile Workstation does not affect the safety, efficacy and performance of OPTIS Integrated System. The results of this testing concludes the OPTIS Integrated System with Mobile Workstation is determined to be safe and effective and is substantially equivalent to the OPTIS Integrated System predicate device.