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

June 29, 2016

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

Re: K160878
Trade/Device Name: Optis™ Metallic Stent Optimization E.4 SW
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ
Dated: April 18, 2016
Received: April 20, 2016

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.

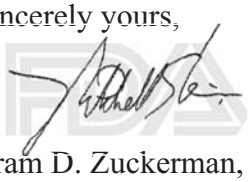
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160878

Device Name
OPTIS Metallic Stent Optimization E.4 SW

Indications for Use *(Describe)*
The OPTIS™ Software 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™ Software 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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Lightlab Imaging, Inc.
OPTIS METALLIC STENT OPTIMIZATION E.4 SW
510(k) Summary
(Per 21 CFR 807.92(c))

1. SPONSOR/MANUFACTURER

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

Contact Person: Padmini Suravaram
Telephone: 978-577-3483

Date Prepared: 03/28/16

2. DEVICE NAME

Proprietary Name:	OPTIS™ Metallic Stent Optimization E.4 SW
Common/Usual Name:	Ultrasonic pulsed echo imaging system
Classification Name:	Ultrasonic pulsed echo imaging system

3. PREDICATE DEVICE

Predicate Device: Lightlab Imaging, Inc. OPTIS™ Mobile System, K152120

4. DEVICE DESCRIPTION

The Metallic Stent Optimization SW E.4 is an OCT system software that allows update of the current software version of ILUMIEN OPTIS (K150878), OPTIS Mobile System (K152120) and OPTIS Integrated OCT Systems (K151286) on the field for the Stent Optimization Tool features. The Metallic Stent Optimization SW E.4 is also compatible with flush catheters compatible with the above mentioned OCT systems (Dragonfly OPTIS and Dragonfly DUO catheters).

The OCT system software is used to control the OCT imaging engine in order to acquire OCT images, it is used to make measurements based on acquired OCT images, it is used to maintain a database of OCT images and data, and it is used to review previously acquired OCT images and data.

The OCT System software is also used to control the Aortic (AO) and PressureWire (PW) USB receivers to collect and store pressure waveform data for computing Fractional Flow Reserve (FFR). Similar to the OCT images, the FFR waveforms are stored in the database and are available for later review.

The OPTIS™ Metallic Stent Optimization E.4 SW software runs on 64-bit Microsoft Windows 7 Embedded Operating System only. The software also contains Intel JPEG Library, Microsoft MPEG-4 Video Codec, Microsoft Video 1 codec, AMD FirePro V4900 Display Adapter Driver, Intel 82579LM/82583V Gigabit Ethernet Controller Driver, Microsoft Foundation Class Library, Active Template Library, Microsoft Standard C++ Library, LEADTOOLS Medical Imaging Suite SDK, Microsoft SQL Server Express 2008 Service Pack 2 (SP2), Open Inventor Library, Haru PDF Library, IDEA Video Driver, iWRAP Bluetooth Stack and Intel Integrated Performance Primitives commercial off the shelf (COTS) software.

The E.4 software introduces the following new features:

- 3D Flythrough, 3D Bifurcation (Bifurcation Visualization)- Enhance assessment of ostium geometry with optimized 3D views
- Cross Frame Angio (Stent Roadmap) - Display stent roadmap with OCT/angiography coregistrations
- Stent Display (Quantification of Stent Strut Apposition, Metallic Stent Visualization) and 3D Display Options (Guide Wire Detection, Side Branch Detection) - Provide intra-procedural guidance by automatic detection and 3D visualization of BMS struts, side branches, and guidewires

INDICATIONS FOR USE

The OPTIS™ Software 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™ Software 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.

5. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The OPTIS™ Metallic Stent Optimization E.4 SW is substantially equivalent in terms of product design, materials of construction, operational and technological features, clinical use, and target population.

Both the proposed OPTIS™ Metallic Stent Optimization E.4 SW and the predicate device OCT System Software perform OCT Image acquisition and FFR. This application is preformed through the System OCT Software. The OPTIS application software and firmware is responsible for controlling the OCT system hardware for the purposes of acquiring raw OCT image data in polar format and scan converting it to raster format for display on the screen using a bilinear interpolation algorithm. This data is stored in a proprietary variant of the TIFF format. The software is also responsible for controlling the FFR hardware for the purposes of acquiring raw aortic and distal pressure waveforms, computing the mean pressure values over a user-defined number of heart cycles, and computing the resulting Fractional Flow Reserve and/or Resting Pd/Pa parameters from the mean pressure waveforms. For both modalities, the software provides storage and retrieval functionality including database storage of the corresponding patient demographic information using the commercial off the shelf SQL Server Express database. The software also enables storage of the OCT and FFR data in a variety of file formats on external DICOM servers.

In addition to providing the basic OCT and FFR modalities, the software contains a number of proprietary OCT image processing algorithms for automatically calibrating the images and segmenting the vessel lumen, side branches, guide wires and metallic stent struts, using a commercial off the shelf volume rendering library (Open Inventor) to provide an interactive 3D display of the image data and segmented objects in a variety of formats. The software also contains a number of proprietary angio image processing algorithms to track the Dragonfly Duo and OPTIS lens marker to provide a complete two dimensional Co-Registration between each OCT frame and each angio frame from simultaneously acquired image sequences.

The OPTIS™ Metallic Stent Optimization E.4 SW represents an upgrade to the predicate device OCT System software in terms of offering the following features:

- Metallic Stent optimization and Stent Apposition Mapping
- Stent Roadmap on Angio Co-registration
- Enhanced 3D Views

- Lumen Profile default is on
- Side-branch display
- Guide wire display
- OCT/Angio export
- Rotational stabilization improvement
- Intravascular OCT (IVOCT) DICOM file format
- Improved Coregistration Workflow
- Improved OCT Frame Indicator on Angio
- Bookmarks Displayed on Angio
- New Home Screen
- Improved DICOM Export Workflow
- XA added to DICOM Modality Worklist Query
- On-Screen Display of Lumen Dimensions
- Scrolling of Full Screen 3D Display

6. PERFORMANCE TESTING

The OPTIS™ Metallic Stent Optimization E.4 SW has been developed and tested in compliance with IEC 62304: 2006 and DICOM Standard: 2015b. 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 in compliance with internal design control procedures.

The results of this testing conclude the OPTIS™ Metallic Stent Optimization E.4 SW is determined to be safe and effective and is substantially equivalent to the predicate OPTIS Mobile System software.