K111201

AUG 10 2011

510(k) SUMMARY

as required per 807.92(c)

Submitter's Name and Address:

LightLab Imaging, Inc.
One Technology Park Drive
Westford, MA 01886

Name, Title, and Telephone Number of Contact:

Bryan Cowell, M.Sc., RAC
Principal Regulatory Affairs Specialist
Tel: (978) 399-1073
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Date submission was prepared: April 28, 2011

Device Name: C7 XR™ Imaging System with Fractional Flow Reserve (FFR) (ILUMIEN Guided Therapy System)

Common Name: Imaging system

Product Code: NQQ
Class: II
Classification Name and Rule: Ultrasonic Pulsed Echo Imaging System

Classification Panel: 21 CFR § 892.1560

Establishment Registration:

Establishment:

LightLab Imaging, Inc.
One Technology Park Drive
Westford, MA 01886

Registration Number: 3004672267

Owner/Operator:
LightLab Imaging, Inc.
One Technology Park Drive
Westford, MA 01886
Owner /Operator Number: 9101521

Legally Marketed Device Identification:

Optical Coherence Tomography Imaging System

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Proposed Device Description:

The C7 XR™ Imaging System K093857 (C7 XR) and Dragonfly™ Imaging Catheter (Dragonfly Catheter or DF) provide images of the coronary arteries in patients who are candidates for transluminal interventional procedures. The system 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 C7 XR will include two USB receivers to accept radiofrequency signals from a distal intracoronary pressure transducer and a proximal aortic pressure transducer and display the acquired pressure waveforms and calculated Fractional Flow Reserve on the C7 XR system monitor.

The C7 with FFR system consists of the following components:

C7 XR Imaging System (K093857): A cart-mounted computer and optical engine control the device and function as user interface, display and data storage. It includes the Drive-motor and Optical Coupler (DOC). The DOC is an optical-electro-mechanical device that provides the optical interconnection between the C7 XR and Dragonfly Catheter, and controls the rotational and axial motion of the fiber-optic core within the catheter and will include two USB receivers to accept radiofrequency signals from the distal intracoronary pressure transducer and a proximal aortic pressure transducer.

Proposed Intended Use:

C7 XR System (K093857) modification for Fractional Flow Reserve

The C7 XR™ Imaging System with C7 Dragonfly™ Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The C7 Dragonfly™ Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The C7 Dragonfly™ 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 C7 XR™ Imaging 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.

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Predicate Devices:

- 510(k) No.: K093857
  Trade Name: C7 XR™ Imaging System with C7 Dragonfly™ Imaging Catheter
  SE Date: 04/30/2010
  Manufacturer: LightLab Imaging, Inc.

- 510(k) No.: K092105
  Trade Name: RadiAnalyzer® Xpress
  SE Date: 10/09/2009
  Manufacturer: Radi Medical Systems AB, Inc.

- 510(k) No.: K080813
  Trade Name: PressureWire®
  SE Date: 7/01/2008
  Manufacturer: Radi Medical Systems AB, Inc.

Substantial Equivalence:

Assessment of non-clinical performance data for equivalence:
The C7 XR™ Imaging System with FFR was tested in accordance with applicable standards and internal design control procedures and was determined to be as safe and effective for its intended use as the predicate device(s).

Assessment of clinical performance data for equivalence:
Clinical performance evaluation (Usability Testing) indicates that the C7 XR™ Imaging System with FFR is substantially equivalent to the predicate devices C7 XR™ Imaging System (K093857) and RadiAnalyzer® Xpress (K092105):

Sterilization:

Not applicable. The C7 XR™ Imaging System with FFR is composed of the C7 XR System which is not supplied sterile. There are no modifications to the Dragonfly catheter in this submission.

Biocompatibility:

Not applicable. The C7 XR™ Imaging System with FFR does not directly contact the patient. If patient contact is made by C7 XR™ Imaging System with FFR it is transient and should be with intact unbroken skin. There are no modifications to the Dragonfly catheter in this submission.

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Standards and Guidance Documentation for reference:

Document Number/Standard	Description
ISO 13485	Medical devices -- Quality management systems -- Requirements for regulatory purposes
ISO 14971	Medical devices -- Application of risk management to medical devices
ISO 15223	Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied
ISO 11607-1	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
ISO 10993	Biological evaluation of medical devices
EN980	Symbols for use in Labeling of Medical Devices
IEC 60601-1	Medical electrical equipment – General requirements for basic safety and essential performance
IEC 60601-1-1	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60825-1	IEC 60825-1 - Part 1: Equipment classification, requirements and user's guide
IEC 62304	Medical device software – Software lifecycle processes
EN 62366	Medical devices. Application of usability engineering to medical devices
EN 60825-1	Safety of laser products – Part 1: Equipment classification and requirements
404P08	Software Development Process
405P02	Software Validation Procedure
IEC 60601-1-4	Medical electrical equipment – Part 1: General Requirements for Safety – Collateral Standard: Programmable electrical medical systems
IEC 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

LightLab Imaging, Inc.
c/o Mr. Bryan Cowell
Principal Regulatory Affairs Specialist
One Technology Park Drive
Westford, MA 01886

AUG 10 2011

Re: K111201
Trade/Device Name: C7 XR Imaging System with Fractional Flow Reserve (FFR)
Regulatory Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: II (two)
Product Code: NQQ
Dated: July 13, 2011
Received: July 15, 2011

Dear Mr. Cowell:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

Indications for Use

510(k) Number (if known): TBD

Device Name: C7 XR™ Imaging System with FFR (Fractional Flow Reserve)

Intended Use:

The C7 XR™ Imaging System with C7 Dragonfly™ Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The C7 Dragonfly™ Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The C7 Dragonfly™ 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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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

0 0013

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111201