K093857

SUMMARY OF SAFETY AND EFFECTIVENESS

1 GENERAL INFORMATION

1.1 Submitter and Owner of the 510(k)

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

APR 30 2010

1.2 Official Correspondent

Christine L. Brauer, PhD
Regulatory Affairs Consultant
7 Trail House Court
Rockville, MD 20850

Telephone: (301) 545-1990
Fax: (301) 545-1992
E-mail: chrisbrauer@earthlink.net

1.3 Date of Preparation

April 30, 2010

1.4 510(k) Application

K093857

2 NAME OF THE DEVICE

2.1 Trade/Proprietary Name

C7 XR™ Imaging System
C7 Dragonfly™ Imaging Catheter and Disposable Accessories

2.2 Common/Usual Name

Imaging system
Intravascular imaging catheter

2.3 Classification Information

Classification Name:	Ultrasonic Pulsed Echo Imaging System Diagnostic Intravascular Catheter

Classification Regulation:	21 CFR § 892.1560 21 CFR § 870.1200
Class:	II II
Product Code:	NQQ ORD
Panel:	Radiology Cardiovascular

3 PREDICATE DEVICES

The predicate devices are the Boston Scientific Galaxy Intravascular Ultrasound System cleared under premarket notification K980851 and the Atlantis™ SR Pro Coronary Imaging Catheter cleared under premarket notification K010707. Together the predicate devices form an imaging system.

4 DESCRIPTION OF THE DEVICE

The C7 XR™ Imaging System (C7 System) and C7 Dragonfly™ Imaging Catheter (Dragonfly Catheter) 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 system consists of the following components:

1. **C7 XR™ Imaging System:** This cart-mounted computer and optical engine control the entire device and function as user interface 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 System and Dragonfly Catheter, and controls the rotational and axial motion of the fiber-optic core within the catheter.

2. **C7 Dragonfly™ Imaging Catheter and Disposable Accessories:** The Dragonfly Catheter is a sterile, single-use catheter that consists of a fiber optic imaging core and an external sheath. The external sheath serves two primary functions: 1) to facilitate placement of the device into the coronary artery, and 2) to cover and protect the inner rotating fiber optic imaging core. The optical fiber imaging core rotates inside the imaging sheath and is driven by a stainless steel torque wire. The optical fiber imaging core delivers near infrared light to the tissue and receives reflected light. The catheter attaches to the DOC, which is covered with a sterile, single-use plastic bag. Image acquisition may be triggered by a sterile, single-use pressure transducer.

3. **Off-line Review Workstation:** The Off-line Review Station consists of a personal computer that incorporates software to allow a healthcare professional to import,

maintain and review images collected by the C7 System and Dragonfly Catheter. The software is a Microsoft Windows XP application running on a host personal computer. It allows healthcare professionals the convenience to review, analyze and maintain OCT images on a personal computer rather than on the C7 System itself, which is located in the catheterization laboratory.

5 INDICATIONS FOR USE AND 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.

6 TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICES

The C7 System and Dragonfly Catheter (the LightLab system) and the predicate devices (predicate system) have some different technological characteristics, but also share many technological characteristics. The primary design difference between the LightLab system and the predicate system is use of a near infrared light versus sound waves for imaging.

The LightLab system and the predicate system share many common design and technological features. Both systems incorporate a disposable, sterile intravascular imaging catheter. Both systems use a computer to control device function, user interface and data storage. Both systems require disposable accessories, including probe covers, for use. A comparison of the similarities of the systems and their components follows.

The LightLab and the predicate systems rely upon an intravascular imaging catheter with a similar design to perform the same functions. Both catheters share similar design features, such as a rapid exchange, mini-rail tip design and similar dimensions. Both catheters facilitate the placement of the device into coronary artery. Both catheters deliver energy to the tissues and collect reflections. The energy source differs between the systems with the LightLab system using near infrared light and the predicate system using sound waves. In both systems, the energy source (sound waves or near infrared light) has different absorption and reflection properties in different tissues and structures, and these differences are used to create an image.

Both the LightLab and predicate systems rely upon a reusable, electronic, software-based unit to control device function, to process electrical signals to produce images, to provide a user interface and display, and to store and manage data. These systems are also responsible for the electro-mechanical-optical interfaces with intravascular imaging catheters. In both systems, the computer system processes patterns and signals received from the intravascular imaging catheters to convert these signals into an image that is displayed.

Both the LightLab and predicate system incorporate a user interface. Both systems provide a series of features for the user. These features include the ability to annotate images and computer aided measurements. Both systems store the collected image data with proper patient identification information and procedural details. Both systems store images in digital format and allow for the review of images after collection.

7 PERFORMANCE TESTING

The 510(k) submission provided performance data to establish the substantial equivalence of the C7 System and Dragonfly Catheter (LightLab system) compared to the predicate devices (predicate system). These performance data included: biocompatibility data, software verification and validation testing, electrical safety, electromagnetic compatibility and laser safety testing, laboratory testing, animal testing and clinical testing.

Biocompatibility: LightLab conducted a series of biocompatibility studies to demonstrate that the catheter device materials are safe, suitable and appropriate for their intended use, and in compliance with two international standards (ISO 10993:1 and ISO 10993:4). The device successfully passed the biocompatibility testing.

Software Testing: LightLab performed system level software verification and validation testing to demonstrate the system performs as intended. The software passed all requirements.

International and Performance Standards: The LightLab system was tested to international safety standards, including electrical and electromagnetic safety testing (EN 60601-1, 60601-3 and 60601-4). The LightLab system was tested and evaluated for its compliance with 21 CFR Part 1040 and internal safety standards for laser products and optical fiber communication systems (IEC 60825). The system met all standards.

Bench (Performance) Testing: LightLab performed a series of bench tests, including physical, mechanical and optical tests, to demonstrate its system meets its performance specifications. The LightLab system passed the test requirements. LightLab also conducted an in vitro study which evaluated the measurement accuracy of its system compared to the predicate system. In this study, LightLab used a simulated model of the coronary vasculature and calibrated arterial phantoms of different sizes. Both the LightLab system and the predicate system were used separately to visualize and measure the arterial phantoms. The results demonstrate that the measurement accuracy of the LightLab system compared favorably to the predicate system. The LightLab system measurements had an error of 3.7% for diameter and 8.6% for area; the corresponding predicate system measurements had an error of 8.3% for diameter and 17.0% for area. These values represent the upper 95^{th} percentile limits of the error distribution for each modality.

Animal Testing: LightLab conducted an animal study to evaluate the safety and effectiveness of its system compared to the predicate system. The LightLab system performed as intended and the histomorphology findings were similar between the two treatment groups (LightLab system versus predicate system).

Clinical Study: LightLab Imaging, Inc. conducted a prospective, multi-center study under a significant risk IDE application to confirm the safety and effectiveness of the LightLab™ C7 XR Imaging System and C7 Dragonfly Imaging Catheter, and to demonstrate its ability to obtain images suitable for the measurement of lumen diameter and cross-sectional area within a stent and artery. The study's primary efficacy endpoint was Clear Image Length, defined as the cumulative length of the OCT pullback containing clear cross-sectional image frames. The study's primary hypothesis was that the true, population median Clear Image Length exceeded 24 mm. Additionally, intra- and inter-observer reliability (variability) of cross-sectional lumen area measurements and Clear Image Length measurements were evaluated. Safety was evaluated based on the incidence of the following events: angina and/or ST segment changes that persist despite treatment, spasm that persists despite treatment, ventricular tachycardia and ventricular fibrillation, angiographic dissection, peri-procedural myocardial infarction, perforation, angiographic no-reflow phenomenon, thrombus formation, distal embolization, emergency coronary artery bypass surgery, and death.

The results demonstrated that the LightLab system was safe and effective for the visualization of coronary arteries. The median Clear Image Length in imaged subjects was 44.0 mm which was statistically significant and close to the maximum (system-limited) pullback length of 50 mm. Substudy variability analyses were conducted which assessed the reliability (variability) of Clear Image Length and cross-sectional lumen area measurements both within one reader and between the two readers. These analyses concluded that both intra- and inter-reader agreements were very good or excellent. Lin Concordance Correlation Coefficients were all 0.95 or greater. None (0/59, 0.0%) of the predefined safety events occurred during the procedure and 3 (3/59, 5.1%) occurred during the post-procedure period. All 3 of these events were peri-procedural, non Q-wave myocardial infarctions and none of them were adjudicated to have been device-related. Regarding adverse events, one (1/59, 1.7%) subject had a serious adverse event which was judged by the DSMB to be related to the procedure but not the device. No subjects died during the clinical study. One (1/59, 1.7%) subject had a device-related adverse event which was sinus bradycardia although this event was not determined to be serious.

8 CONCLUSIONS

This 510(k) submission demonstrates that the C7 System and Dragonfly Catheter are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

LightLab Imaging Inc.
C/O Christine Brauer, Ph.D.
Brauer Device Consultants, LLC
7 Trail House Court
Rockville, MD 20850

APR 30 2010

Re: K093857
Trade Name: C7 XR Imaging System with C7 Dragonfly Imaging Catheter and Disposable Accessories
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ, ORD
Dated: April 26, 2010
Received: April 27, 2010

Dear Dr. Brauer:

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.

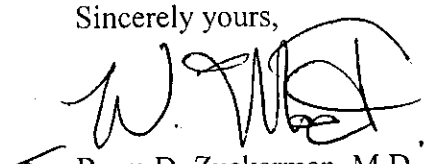
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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 (K093857):

Device Name: C7 XR™ Imaging System

C7 Dragonfly™ Imaging Catheter and Disposable Accessories

Indications for 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.

Prescription Use __x__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093857