K123226

5.0 510(k) Summary

DEC 05 2012

Device Common Name: Interventional Fluoroscopic X-Ray System, Accessory

Device Proprietary Name: LessRay™

Submitter: SafeRay Spine, LLC
5103 Brookstone Dr.
Durham, NC 27713

Contact: Calley Herzog, Consultant to SafeRay Spine
Biologics Consulting Group, Inc.
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Date Prepared: November 30, 2012

Classification Regulation: 892.1650

Panel: Radiology

Product Codes: Primary:
OWB - Interventional Fluoroscopic X-Ray System, Accessory

Additional Product Code:
LLZ - System, Image Processing, Radiological

Predicate Device: K013841 3D Sharp Fluoroscope Image System
(3DFIS – Model IES-FL-101)

Indication for Use:
The LessRay™ is intended for use in any application where a fluoroscope is incorporated to aid in diagnosis and treatment of disease.

Device Description:
The LessRay™ is a stand-alone computer display system interfaced to a fluoroscope with a video cable. The images produced by the fluoroscope are transmitted to a frame grabber in the computer where the images are enhanced and then displayed on the LessRay™ monitor. Each image is displayed on the LessRay™ monitor at the same time as the corresponding original image is displayed on the fluoroscope monitor(s).

Performance Data:
To establish the substantial equivalence of the LessRay™ device the following performance tests were performed:

- Validation Test 1 - Low Dose/Pulse Image Improvement
- Validation Test 2 - Blocked Anatomy
- Validation Test 3 - Parallax Test
- Validation Test 4 – Pig Study

The LessRay™ system meets the following Electrical Safety and EMC standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests

Substantial Equivalence Discussion:
The LessRay™ System is substantially equivalent to the 3DSharp Fluoroscope Image System (3DFIS) K013841. The 3DFIS is also designed to capture multiple images, manipulate the images arithmetically, and display the generated reduced noise images.
The differences between the LessRay™ System and the 3DFIS are that the LessRay™ System, the LessRay™ System can merge sequential and non-sequential images of the same anatomy to enhance image quality, while the 3DFIS merges only sequential images to enhance image quality. An additional difference is that the 3DFIS uses an algorithm similar to a Fourier transform to enhance image quality, while the LessRay™ System uses an averaging algorithm to use full-dose images to enhance image quality. Although the LessRay™ and 3DFIS use different mathematical methods to improve image quality, the results of validation testing demonstrate that the LessRay™ provides accurate and clinically relevant images. Therefore performance testing demonstrates that the LessRay™ is as safe and effective as the 3DFIS.

Substantial Equivalence Conclusion:
Based on the identical indication, similar technological characteristics, and results of performance testing, the LessRay™ is substantially equivalent to the 3D Sharp Fluoroscope Image System (3DFIS – Model IES-FL-101) as it was cleared in K0138413DFIS as it was cleared in K013841.

A detailed comparison is provided in the Table below:

Device Characteristic	Predicate Device	Subject Device
510(k) Number	K013841	-
Device Name	3DFIS, MODEL IES-FL-101	LessRay™
Manufacturer	3DSHARP, INC.	SafeRay Spine, LLC
Computer	Dual G4 Power Mac	Intel Core 2 Duo Processor, 8GB
Frame Grabber	Scion Corp, Model CG7	Hybrid ATSC/QAM/Analog F2 Type Minicard w/10-pin AV-Input
Monitor	Apple 15" Flat Screen	17" LCD Touch Screen

Device Characteristic	Predicate Device	Subject Device
Operation System	MacOS 9.1	Windows 7
Image Processing Speed	30 frame/sec	10.6 frame/sec
Delay between frame acquisition	33msec	33msec
Indication	Indicated for use in any application where a fluoroscope is incorporated to aid in diagnosis and treatment of disease.	Indicated for use in any application where a fluoroscope is incorporated to aid in diagnosis and treatment of disease.
Stand-alone computer and monitor	Yes	Yes
Displays unaltered image from fluoroscope	Yes	Yes
Displays reduced noise images	Yes	Yes
For use during procedures that involve fluoroscopy	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

SafeRay Spine, LLC
% Ms. Calley Herzog
Consultant
Biologics Consulting Group, Inc.
13417 Quivas St.
WESTMINSTER CO 80234

December 5, 2012

Re: K123226
Trade/Device Name: LessRay™
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and LLZ
Dated: October 15, 2012
Received: October 24, 2012

Dear Ms. Herzog:

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,

Michael D. O'Hara

Janine M. Morris, M.S.
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

4.0 Indications for Use Statement

510(k) Number (if known):_____

Device Name: LessRay™

Indications For Use:

The LessRay™ is intended for use in any application where a fluoroscope is incorporated to aid in diagnosis and treatment of disease.

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 IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k) K123226

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