K132970
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510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the LessRay® is provided below.

Device Common Name:	Interventional Fluoroscope X-Ray System, Accessory
Device Proprietary Name:	LessRay®
Submitter:	SafeRay Spine, LLC 5012 Chapel Hill Durham Blvd. Suite 203 Durham, NC 27707
Contact:	Calley Herzog Consultant, Medical Devices Biologics Consulting Group, Inc. Phone: 720-883-3633 Fax: 720-293-0014 Email: cherzog@bcg-usa.com
Alternate Contact:	Donna-Bea Tillman, Ph.D. Biologics Consulting Group, Inc. Phone: 410-531-6542 Email: dtillman@bcg-usa.com
Date Prepared:	September 19, 2013
Classification Regulation:	21 CFR 892.1650
Panel:	Radiology
Product Code:	OWB
Predicate Device:	K123226 – Submitter's own previously cleared device

NOV 29 2013

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:

LessRay® is a software only device that is used to enhance the utility of low dose images by comparing them to a baseline image taken at a regular dose setting. A computer running LessRay® is 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 monitor of the computer running LessRay®. Each image is displayed by LessRay® at the same time as the corresponding original image is displayed on the fluoroscope monitor(s).

Performance Data:

The subject of this 510(k) is a modification to the previously cleared LessRay® System. The LessRay device that was previously cleared in K123226 was provided preloaded on a computer system. The only modification to the device since its previous clearance is that the software will now be provided on a CD for installation by the end user onto a computer that meets the stated specifications. These modifications represent a minor device modification and do not affect the indications for use. To assess the impact of this change a risk analysis was conducted. Based on the risk analysis verification testing was performed to ensure proper functioning of the software on four computer platforms. Each of the four computer platforms tested meet the specifications of the LessRay® System as previously cleared.

Substantial Equivalence:

The modification of the LessRay® System to not provide it on a pre-loaded computer does not change the fundamental technology of the device or the intended use of the device. The algorithm used and the user experience are identical to that of the previously cleared version. Based on technological characteristics and indication for use, the modified device is substantially equivalent to the previously cleared LessRay® System.

Table 1: Device Comparison Table

	Proposed Device	**Predicate Device**
510(k) Number	K132970	K123226
Submitter	SafeRay Spine, LLC	SafeRay Spine, LLC
Classification Regulation	892.1650	892.1650
Product Code	OWB, LLZ	OWB, LLZ
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.

	Proposed Device	Predicate Device
Compatible Hardware Platforms	**1. ONYX 175z** CPU: Intel Core 2 Duo GPU: NVIDIA Quadro 4000 RAM: 8 GB HDD: 500 GB Frame Grabber: Aver Media H339 Windows 7 **2. Sony VAIO L Series** CPU: Intel Core i7 GPU: NVIDIA GeForce 640M RAM: 8 GB HDD: 500 GB Frame Grabber: El Gato Windows 8 **3. Maxant Mediport 3000** CPU: Intel Core i7 GPU: NVIDIA GTX660TI RAM: 8 GB HDD: 512 GB Frame Grabber: El Gato Windows 7 **4. Dell Precision M6700** CPU: Intel Core i5 GPU: NVIDIA Quadro k3000M RAM: 8 GB HDD: 750 GB Frame Grabber: El Gato Windows 7	**1. ONYX 175z** CPU: Intel Core 2 Duo GPU: NVIDIA Quadro 4000 RAM: 8 GB HDD: 500 GB Frame Grabber: Aver Media H339 Windows 7
Software is Run on a stand-alone computer and monitor	Yes	Yes
Device is passive and doesn't control the fluoroscope	Yes	Yes
Displays reduced noise images	Yes	Yes
For use during procedures that involve fluoroscopy	Yes	Yes
Improves quality of low does images	Yes	Yes
Uses data from prior images to improve quality of subsequent images	Yes	Yes
Algorithm used to improve image quality	NO CHANGE from K123226	Summation of prior full dose images with subsequent images

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

November 29, 2013

SafeRay Spine, LLC
% Ms. Calley Herzog, Consultant
Biologics Consulting Group, Inc.
400 N. Washington Street, Suite 100
ALEXANDRIA VA 22314

Re: K132970
Trade/Device Name: LessRay®
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, LLZ
Dated: November 6, 2013
Received: November 7, 2013

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 contact 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. 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 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,

Robert A Ochs

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132970

Device Name
LessRay(R)

Indications for Use *(Describe)*
The LessRay® is intended for use in any application where a fluoroscope is incorporated to aid in diagnosis and treatment of disease.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Robert A Ochs