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

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

November 18, 2014

Re: K142243
Trade/Device Name: LessRay with Tracking
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA, LLZ
Dated: October 17, 2014
Received: October 20, 2014

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 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,

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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K142243

Device Name
LessRay® with Tracking

Indications for Use *(Describe)*
LessRay® with Tracking 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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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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 with Tracking is provided below.

| | |
|---|---|
| **Device Common Name:** | Image Processing System |
| **Device Proprietary Name:** | LessRay® with Tracking |
| **Submitter:** | SafeRay Spine, LLC<br>5102 Durham Chapel Hill Blvd., Suite 203<br>Durham, NC 27707<br>Phone: 877-814-7509 |
| **Contact:** | Calley Herzog<br>Consultant<br>Biologics Consulting Group, Inc.<br>Phone: 720-883-3633<br>Fax: 703-548-7457<br>Email: cherzog@bcg-usa.com |
| **Classification Regulation:** | 21 CFR 892.1650, Class II |
| **Classification Name:** | Image-intensified fluoroscopic x-ray system |
| **Panel:** | Radiology |
| **Primary Product Code:** | OWB - interventional fluoroscopic x-ray system |
| **Secondary Product Codes:** | LLZ – system, image processing, radiological |
| | JAA – system, x-ray, fluoroscopic, image-intensified |
| **Date Prepared:** | October 17, 2014 |
| **Predicate Device:** | K132970, LessRay® |

**Indication for Use:**

LessRay® with Tracking 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 application which can be interfaced to a fluoroscope with a video cable. The images produced by the fluoroscope are transmitted to a frame grabber in the computer running LessRay® where the images are enhanced and then displayed. When used in connection with the low dose and/or pulse setting on the fluoroscope, the user can improve the quality (clarity, contrast, noise level, and usability[1]) of a noisy (low-quality) image. Using this system, much of the graininess of low radiation dose images can be eliminated. This allows for greater utility of low dose imaging.[2]

LessRay® works by combining the current image being taken with a prior "Baseline" image of the same anatomy. The initial image, taken at regular radiation dose settings, serves as a baseline to which images taken at lower dose radiation settings can be compared and enhanced.

In procedures where instruments are introduced into the field of view, LessRay® images provide information that is not available with conventional images. By merging an image of interest containing tools with the unencumbered Baseline image, the radio dense metallic tools and implants that obscure the underlying anatomy can be rendered partially translucent in the merged image. In addition, by alternating the new image with the Baseline a user can make these metallic tools or implants disappear and reappear from the image, revealing the anatomy blocked by the tool.

The subject of this 510(k) is the addition of tracking capability to be used with LessRay®. LessRay® can be interfaced with a tracking system in order to aid the C-arm technician in positioning the fluoroscope between the various views of the patient necessary for the intervention. LessRay® with Tracking ensures that the fluoroscope is centered over the correct anatomy prior to taking any additional x-ray images.

**Performance Data:**

To establish the substantial equivalence of the modified LessRay® with Tracking to the predicate LessRay® device, the following performance tests were performed:

- Regression/Image Recognition Compared to LessRay v1.0
- Verification of Glyph Tracking
- Tracking Accuracy with the NDI Vicra Optical Tracking System
- Tracking Accuracy with the Patriot M Electromagnetic Tracking System
- Tracking Accuracy with the Patriot M Electromagnetic Tracking System and Dynamic Metal Distortion
- Collar Assembly Vertical Pull-Off Safety Test
- Validation of Fluoroscope Navigation

**Substantial Equivalence:**

Based on the identical indication, similar technological characteristics, and results of performance testing, LessRay® with Tracking is substantially equivalent to the previously cleared LessRay® device (K123226).

**Table 1: Device Comparison Table**

| | **Proposed Device** | **Predicate Device** |
|---|---|---|
| **510(k) Number** | K142243 | K132970 |
| **Device Name** | LessRay® with Tracking | LessRay® |
| **Submitter** | SafeRay Spine, LLC | SafeRay Spine, LLC |
| **Classification Regulation** | 892.1650 | 892.1650 |
| **Product Code** | OWB, LLZ | OWB, LLZ |

| | Proposed Device | Predicate Device |
|---|---|---|
| **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. |
| **Compatible Hardware Platforms** | Any computer that meets the following minimum specifications:<br>CPU: Intel Core 2 Duo<br>GPU: NVIDIA Quadro 4000<br>RAM: 8 GB<br>HDD: 256 GB<br>Frame Grabber: Aver Media H339 or Elgato<br>Operating System: Windows 7 or 8.1 | Any computer that meets the following minimum specifications:<br>CPU: Intel Core 2 Duo<br>GPU: NVIDIA Quadro 4000<br>RAM: 8 GB<br>HDD: 256 GB<br>Frame Grabber: Aver Media H339 or Elgato<br>Operating System: Windows 7 or 8.1 |
| **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 dose images** | Yes | Yes |
| **Uses data from prior images to improve the quality of subsequent images** | Yes | Yes |
| **Algorithm used to improve image quality** | Summation of prior full dose images with subsequent images | Summation of prior full dose images with subsequent images |
| **Provides visual cues which help guide the user in positioning the C-arm back to where a prior Baseline was taken.** | Yes | No |
| **Automatically selects the nearest Baseline as the C-arm is being moved.** | Yes | No |
| **Requires a 6 DOF tracking system in some configurations.** | Yes | No |

| | Proposed Device | Predicate Device |
|---|---|---|
| **Requires mounting hardware used to mount the 6 DOF tracking system to the C-arm and the operating table.** | Yes | No |

## Substantial Equivalence Summary

The addition of the optional tracking feature does not change the intended use of the device as a software application that enhances images from a fluoroscope. LessRay® with Tracking provides the additional capability of aiding the user in acquiring fluoroscopic images by ensuring that the fluoroscope is centered over the correct anatomy prior to taking any additional x-ray images. The performance testing demonstrated substantial equivalence of LessRay with Tracking to the previously cleared LessRay device. Therefore, based on the identical indication, similar technological characteristics, and results of performance testing, LessRay® with Tracking is substantially equivalent to LessRay® as it was cleared in K123226 and K132970.

[1]As evaluated by a human observer in a side by side visual comparison of 30 image pairs with and without LessRay processing.

[2] In clinical practice, the amount of image quality improvement achieved when a Pulsed and/or Low Dose image is processed with LessRay is dependent on the clinical task, patient size, anatomical location, and clinical practice. The dose should be set at a level to which the physician is able to achieve the adequate image quality needed for the particular clinical task. A consultation with a radiologist and a physicist may aid in determining the appropriate dose settings.