



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

NuVasive, Incorporated
% Manthan Damani
Senior Regulatory Affairs Specialist
7475 Lusk Boulevard
SAN DIEGO CA 92121

August 18, 2017

Re: K170800

Trade/Device Name: NuVasive[®] LessRay[®] with Enhanced Tracking
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, LLZ and JAA
Dated: July 25, 2017
Received: July 26, 2017

Dear Manthan Damani:

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a large, light blue, semi-transparent watermark of the letters "FDA". To the right of the signature, the word "For" is printed in a small, black, sans-serif font.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K170800

Device Name

NuVasive® LessRay® with Enhanced Tracking

Indications for Use (Describe)

NuVasive® LessRay® with Enhanced 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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 Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

Manthan J. Damani
Senior Regulatory Affairs Specialist
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800

Date Prepared: August 17, 2017

B. Device Name

Trade or Proprietary Name:	NuVasive® LessRay® with Enhanced Tracking
Common or Usual Name:	Image processing system
Classification Name:	Image-intensified fluoroscopic x-ray system
Device Class:	Class II
Classification:	21 CFR § 892.1650
Product Code:	OWB, LLZ, JAA

C. Predicate Devices

The subject device is substantially equivalent to the predicate device LessRay® with Tracking (K142243).

D. 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 usability¹) 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 with Tracking provided the additional feature of being able to interface LessRay 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.

NuVasive LessRay with Enhanced Tracking has additional capability of instrument tracking to aid the user in positioning an instrument using prior baseline x-rays. A tracker is attached to the instrument and as the instrument moves, the tracking system connected to LessRay tracks the location of the instrument. NuVasive LessRay with Enhanced Tracking uses this information to aid the user in positioning the instrument.

NuVasive LessRay with Enhanced Tracking is designed per recommendations provided in the following FDA guidance documents:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Off-The-Shelf Software Use in Medical Devices
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

E. Indications for Use

NuVasive® LessRay® with Enhanced Tracking is intended for use in any application where a fluoroscope is incorporated to aid in diagnosis and treatment of disease.

F. Comparison of Technological Characteristics with Predicate Device

As was established in this submission, the subject NuVasive LessRay with Enhanced Tracking is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent to its predicate device through comparison in areas including design, labeling/intended use, and function.

Specification / Property	Predicate Device	Subject Device	Discussion
	LessRay with Tracking (K142243)	NuVasive LessRay with Enhanced Tracking	
Intended Use / Indications for Use	<i>LessRay® with Tracking</i> is intended for use in any application where a fluoroscope is incorporated to aid in diagnosis and treatment of disease.	<i>NuVasive® LessRay® with Enhanced Tracking</i> is intended for use in any application where a fluoroscope is incorporated to aid in diagnosis and treatment of disease.	Same
Device Class	II	II	Same
Product Code	OWB, JAA, LLZ	OWB, JAA, LLZ	Same
Regulation Number (21CFR)	§892.1650	§892.1650	Same
Device Classification Name	Interventional Fluoroscopic X-Ray System	Interventional Fluoroscopic X-Ray System	Same

Specification / Property	Predicate Device	Subject Device	Discussion
	LessRay with Tracking (K142243)	NuVasive LessRay with Enhanced Tracking	
Device Functionalities (image acquisition, enhancement, and display)	<ul style="list-style-type: none"> - Software based device used to provide computer display systems interfaced to a fluoroscope through a video cable. The images produced by the fluoroscope are transmitted through a cable to a frame capture board in the computer where the images are enhanced and then displayed on the monitor. - Enhanced images are displayed on a computer monitor at the same time that the corresponding original image is displayed on the fluoroscope monitor(s). - Serves only as an image display which is in addition to the fluoroscope's standard image display device. Device is passive, in that the operation depends only on the video output of the fluoroscope, and it does not transmit any signals or images to the fluoroscope. 	<ul style="list-style-type: none"> - Software based device used to provide computer display systems interfaced to fluoroscope through a video cable. The images produced by the fluoroscope are transmitted through a cable to a frame capture board in the computer where the images are enhanced and then displayed on the monitor. - Enhanced images are displayed on a computer monitor at the same time that the corresponding original image is displayed on the fluoroscope monitor(s). - Serves only as an image display which is in addition to the fluoroscope's standard image display device. Device is passive, in that the operation depends only on the video output of the fluoroscope, and it does not transmit any signals or images to the fluoroscope. 	Same
Algorithms	<ul style="list-style-type: none"> - Image quality improvement using averaging algorithm - Contrast and brightness enhancement with simultaneous reduction of random noise 	<ul style="list-style-type: none"> - Image quality improvement using averaging algorithm - Contrast and brightness enhancement with simultaneous reduction of random noise 	Same
Compatible hardware platforms	<p>Any computer that meets the following minimum specifications:</p> <p>CPU: Intel Core 2 Duo GPU: NVIDIA Quadro 4000 RAM: 8 GB HDD: 256 GB Frame Grabber: Aver Media H339 or Elgato Operating System: Windows 7 or 8.1</p>	<p>Any computer that meets the following minimum specifications:</p> <p>CPU: Intel Core 2 Duo GPU: NVIDIA Quadro 4000 RAM: 8 GB HDD: 256 GB Frame Grabber: Aver Media H339 or Elgato Operating System: Windows 8.1</p>	same

Specification / Property	Predicate Device	Subject Device	Discussion
	LessRay with Tracking (K142243)	NuVasive LessRay with Enhanced Tracking	
C-arm Tracking	<ul style="list-style-type: none"> - When tracking is enabled, will automatically choose the Baseline when the fluoroscope is near the location and orientation that the Baseline was initially taken. - When tracking is enabled, requires hardware components in order to mount the off-the-shelf tracking hardware to the C-arm and to the operating table. - When tracking is enabled, requires the use of an off-the-shelf tracking system in order to track the 6 DOF location of the C-arm relative to the operating table. - When tracking is enabled, visual cues are provided which help guide the user in positioning the C-arm back to where a prior Baseline was taken. 	<ul style="list-style-type: none"> - When tracking is enabled, will automatically choose the Baseline when the fluoroscope is near the location and orientation that the Baseline was initially taken. - When tracking is enabled, requires hardware components in order to mount the off-the-shelf tracking hardware to the C-arm and to the operating table. - When tracking is enabled, requires the use of an off-the-shelf tracking system in order to track the 6 DOF location of the C-arm relative to the operating table. - When tracking is enabled, visual cues are provided which help guide the user in positioning the C-arm back to where a prior Baseline was taken. 	Same
Tracking options	Electromagnetic or optical	Electromagnetic or optical	Same
Instrument Tracking	No	Yes- NuVasive LessRay with Enhanced Tracking has additional capability of instrument tracking to aid the user in positioning an instrument using prior baseline x-rays.	Additional functionality

G. Performance Data

Nonclinical testing was performed to demonstrate that the subject NuVasive LessRay with Enhanced Tracking is substantially equivalent to the predicate device. The following testing was performed:

- Verification of Instrument Tracking to confirm that subject device allows the user to position the instrument back to where it was located when the desired image is taken.
- Verification of Graphical User Interface (GUI) to confirm that the GUI performs according to specifications.
- Validation of Instrument Tracking to confirm that using subject device instruments can be relocalized with less number of x-ray images, greater accuracy, and less time than when using conventional fluoroscopy.

- Regression Testing to verify image alignment, glyph tracking, and image registration performance functionalities.

The results demonstrate that the subject NuVasive LessRay with Enhanced Tracking is substantially equivalent to the predicate.

H. Conclusions

The subject NuVasive LessRay with Enhanced Tracking has been shown to be substantially equivalent to legally marketed predicate devices for their intended use.

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.