February 28, 2018

TrackX Technology, LLC
% Calley Herzog
Senior Consultant
Biologics Consulting Group, Inc.
1555 King Street, Suite 300
ALEXANDRIA VA 22314

Re: K173736
Trade/Device Name: TrackX
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, LLZ and JAA
Dated: February 2, 2018
Received: February 5, 2018

Dear Calley 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173736

Device Name
Track X

Indications for Use *(Describe)*
TrackX 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

1. SUBMITTER

Submitter:	TrackX Technology, LLC 5102 Durham Chapel Hill Blvd. Suite 203 Durham, NC 27707 Tel: 888-787-2259
Contact Person:	Robert Isaacs robert.isaacs@trackx.tech
Submission Correspondent:	Calley Herzog Senior Consultant Biologics Consulting Group, Inc. 1555 King St., Suite 300 Alexandria, VA 22314 (720) 883-3633 cherzog@biologicsconsulting.com
Date Prepared:	December 5, 2017

2. DEVICE

Name of Device:	TrackX
Common or Usual Name:	Image processing system
Regulation Name:	Image-intensified fluoroscopic x-ray system 21 CFR § 892.1650
Regulatory Class:	Class II
Classification Product Code: **Subsequent Product Codes:**	OWB LLZ, JAA

3. PREDICATE DEVICE

Predicate Device Name:	NuVasive LessRay with Enhanced Tracking
Regulation Name:	Image-intensified fluoroscopic x-ray system 21 CFR § 892.1650

Regulatory Class:	Class II
Classification Product Code: **Subsequent Product Codes:**	OWB LLZ, JAA
Manufacturer:	NuVasive, Incorporated
510(k) Number:	K170800
Reference Devices:	No reference devices were used in this submission.

4. DEVICE DESCRIPTION

TrackX is a software application which captures diagnostic images using a fluoroscope via a video cable. In addition, TrackX interfaces with an off-the-shelf tracking system in order to track the position of surgical instruments relative to the fluoroscope. The user controls and views information via a primary monitor. The viewing monitor is not part of the subject device.

TrackX will track the location of the tip of a surgical instrument. Instrument tracking is accomplished using either an electromagnetic or optical tracking system with one tracker mounted on the surgical instrument and another tracker mounted on the fluoroscope. When used with an electromagnetic tracking system, Civco's eTRAX Needle Tip Tracking system is used. When used with an optical tracking system, TrackX snaps are used.

The tracking information is then fed into the TrackX software which manipulates the location of an X-ray image based on movement of the tracked surgical instrument. Instrument tracking aids the physician in repositioning their surgical instruments by providing visual feedback on where they have moved their instruments between X-ray images. Additionally, TrackX can register the current image being taken (which contains the surgical instrument) with a prior Baseline image of the same anatomy and then use the Baseline image as a Background which the current image is translated over as part of instrument tracking.

TrackX can be used with either electromagnetic tracking or optical tracking. The C-arm tracking feature of the predicate device creates a viewfinder for the fluoroscope which allows the user to track the C-arm movement as they localize and relocalize the fluoroscope during an intervention. While TrackX does not provide this feature, it is still necessary to mount components to the C-arm so that its position can be tracked. The C-arm's tracked position is used to detect the C-arm's orientation and to track the position of instruments relative to the C-arm.

TrackX 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

- Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices

5. INDICATION FOR USE

The indications for use statement is identical to that of the predicate device:

> TrackX is intended for use in any application where a fluoroscope is incorporated to aid in diagnosis and treatment of disease.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The markers TrackX snaps used with the TrackX software are identical to markers used with the predicate device.

The predicate device is the NuVasive LessRay with Enhanced Tracking as cleared in K170800.

As described in K170800, the NuVasive LessRay with Enhanced Tracking system provides three core features: image enhancement, c-arm tracking, and instrument tracking. TrackX, the subject device of this 510(k), only includes the instrument tracking feature, in which TrackX uses the tracked location of the tip of a surgical instrument to provide visual cues to the user in repositioning the instrument (image enhancement and c-arm tracking are not included in TrackX). TrackX uses the same codebase as the instrument tracking component of the NuVasive LessRay with Enhanced Tracking system cleared in K170800. Therefore, the information provided in the submission supports the substantial equivalence of the TrackX instrument tracking system to the instrument tracking functionality cleared in the NuVasive LessRay with Enhanced Tracking, K170800.

	Proposed Device	**Predicate Device**
510(k) Number	K173736	K170800
Submitter	TrackX Technology, LLC	NuVasive, Incorporated
Classification Regulation	892.1650 - Image-intensified fluoroscopic x-ray system	892.1650 - - Image-intensified fluoroscopic x-ray system
Classification Product Code	OWB - interventional fluoroscopic x-ray system	OWB - interventional fluoroscopic x-ray system
Subsequent Product Codes	JAA - system, x-ray, fluoroscopic, image-intensified LLZ - system, image processing, radiological	JAA - system, x-ray, fluoroscopic, image-intensified LLZ - system, image processing, radiological
Device Class	2	2
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	Any computer that meets the following minimum specifications: CPU: Intel i5 GPU: NVIDIA 760 RAM: 8 GB HDD: 256 GB Frame Grabber: Aver Media H339 or Elgato Operating System: Windows 10	Any computer that meets the following minimum specifications: 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
Software is run on a stand-alone computer and monitor	Yes	Yes
Device is passive and doesn't control the fluoroscope	Yes	Yes
For use during procedures that involve fluoroscopy	Yes	Yes
Provides visual cues which help guide the user in positioning the instrument back to where it was when a prior x-ray image of it was taken.	Yes	Yes
Requires a tracking system when tracking is being used.	Yes	Yes
Requires a tracker to interface with the tracking system.	Yes	Yes
Requires a sterile tracker attached to the instrument in order to track the location of the tip of the surgical instrument	Yes (TrackX Snaps – identical to the NuX Snaps used with predicate)	Yes
Enhances x-ray images taken by the fluoroscope.	*No*	Yes
Provides visual cues which help guide the user in positioning the fluoroscope back to where it was when a prior x-ray image was taken.	*No*	Yes

The differences between the subject device and the predicate device do not change the fundamental technology or the intended use of the device. Therefore, based on the identical

indication, similar technological characteristics, and results of performance testing, TrackX is substantially equivalent to the NuVasive LessRay with Enhanced Tracking as cleared in K170800.

7. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility

There are no direct or indirect patient-contacting components of the subject device. Therefore, biocompatibility testing is not needed for this device.

Sterilization and Shelf Life

Like the predicate device, the only sterile components are the TrackX Snaps that are attached to the instrument. The TrackX Snaps are identical to the NuX Snaps cleared in K170800. No changes have been made to the snaps, their packaging or the sterilization methods. Therefore, the information provided in K170800 is applicable to the subject device.

TrackX Snaps are provided sterile, for single use only, and labeled with a three-year shelf life. The snaps are sterilized using Gamma sterilization, and the sterilization method has been validated in accordance with AAMI/ISO 11137-1 Sterilization of health care products – Radiation – Part 1: Requirements for development, validation, and routine control of sterilization process for medical devices (2006) to demonstrate a Sterility Assurance Level (SAL) of 10^{-6}.

Accelerated aging tests were conducted to support a three-year shelf life on samples having been packaged and sterilized to a single (validated) sterilization cycle. The validated cycle includes a minimum of 25 kGy and a maximum of 40 kGy exposure and is the same process used to sterilize the final device.

When used with an electromagnetic tracking system, Civco's eTRAX Needle Tip Tracking system is used. The eTRAX system is purchased off the shelf and is not provided as part of the TrackX System. No changes are made to the eTRAX Needle System for its use with TrackX and it is used in accordance with its off the shelf labeling. Sterilization and shelf life information can be obtained in the instructions for use provided with the eTRAX system.

Electrical Safety and Electromagnetic Compatibility (EMC)

The components of TrackX are software and hardware mounting components only. Use of TrackX includes a fluoroscope, a general-purpose computer and a compatible tracking system, which are all off-the-shelf components provided by the end user. The use of the TrackX software and hardware mounting components would have no impact on EMC or Electrical Safety. Therefore, EMC and Electrical Safety evaluation was not required by FDA for the predicate device, and is not applicable for the subject device.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of

Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

Bench Testing

Instrument Tracking with Optical

The purpose of this testing was to verify that TrackX with the Polaris optical tracking system is able to guide the user back to the location where the instrument was in the previous X-ray image so that the instrument is close enough to original location to perform a medical intervention. The testing demonstrated that TrackX met specifications.

Instrument Tracking with EM

The purpose of this testing was to verify that TrackX with the Ascension electromagnetic tracking system is able to guide the user back to the location where the instrument was in the previous X-ray image so that the instrument is close enough to original location to perform a medical intervention. The testing demonstrated that TrackX met specifications.

Glyph Tracking Regression Test

The purpose of this testing was to verify that the digital rotation and reflection of the fluoroscope image can be tracked with the glyph detection function in TrackX. The results demonstrated that the glyph detection meets the requirements for accuracy, precision, and speed required by TrackX, as specified in the Software Requirement Specification.

Image Registration Performance Regression

The purpose of this testing was to verify that when the TrackX software is installed on a computer, it can perform Image Registration within time and resolution constraints specified in the Software Requirement Specification. For all computer platforms tested, TrackX was able to display and register images well within the required speeds.

Image Registration Regression

TrackX uses the same codebase as the instrument tracking component of the NuVasive LessRay with Enhanced Tracking system cleared in K170800. The purpose of this regression testing was to verify that the changes introduced to the code in the transition from the previously cleared LessRay to TrackX do not adversely affect the ability of TrackX to register images. The results of the study demonstrated that the image registration algorithm performs the same in the subject as it does in the predicate device. Both algorithms correctly registered images that should be registered and rejected images that should not be registered. Studies on live pigs and parallax studies provided with the predicate LessRay submission demonstrate that TrackX is able to register a static baseline with an X-ray taken under conditions where the anatomy is moving or where the fluoroscope or patient have been moved. The studies demonstrate that TrackX is capable of working during interventions on living animals, with patient shift, and with organ/structure motion.

Clinical Study

Not applicable. Clinical studies are not necessary to establish the substantial equivalence of this device.

8. CONCLUSIONS

As described above, based on the Indication for Use identical to the predicate device, similar technological characteristics, and results of performance testing, TrackX is substantially equivalent to the NuVasive LessRay with Enhanced Tracking as cleared in K170800.