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

March 5, 2020

Re: K200360
Trade/Device Name: TrackX v.2.0
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, LLZ, JAA
Dated: February 12, 2020
Received: February 13, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*
K200360

Device Name
TrackX v.2.0

Indications for Use *(Describe)*
TrackX v.2.0 is intended for use in any application where a fluoroscope is incorporated to aid in the 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K200360 - 510(K) SUMMARY

1. SUBMITTER

Submitter:	TrackX Technology, LLC 200 Timberhill Place, Suite 223 Chapel Hill, NC 27514 Tel: 888-787-2259
Contact Person:	David Skwerer Tel: 888-787-2259 david.skwerer@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:	March 4, 2020

2. DEVICE

Name of Device:	TrackX v.2.0
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:	TrackX
Manufacturer:	Track X Technology, LLC

510(k) Number:	K173736
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
Reference Devices:	No reference devices were used in this submission.

4. DEVICE DESCRIPTION

TrackX is a software application which captures diagnostic images from 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. TrackX works by translating and rotating an X-ray image which contains the surgical instrument on the screen based on the surgeon's movement of the instrument. This real-time feedback allows the physician to reposition the instrument with greater accuracy between X-ray images. This aids the physician in repositioning their surgical instruments by providing visual feedback on where they have moved their instruments between X-ray images.

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 predicate device is the submitter's own Track X as cleared in K173736. The purpose of this 510(k) is to acquire clearance of two new features, Projection and Home Base Selector.

The markers used with the TrackX software are identical to the snaps used with the predicate device with additional snaps noted in letters to file.

	Proposed Device	**Predicate Device**
510(k) Number	K200360	K173736
Submitter	TrackX Technology, LLC	TrackX Technology, LLC
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
Indications	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: CPU: Intel i5 GPU: NVIDIA 760 RAM: 8 GB HDD: 256 GB Frame Grabber: Aver Media H339, Elgato or Accustream Operating System: Windows 10	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
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

	Proposed Device	Predicate Device
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	Yes
Allows the user to select which tracked object is the origin relative to which the C-arm and Instruments are tracked. (Home Base Selector)	Yes	No
Provides a measurement off of a reference point in the X-ray image. (Projection)	Yes	No

The modifications described above do not change the fundamental technology or the intended use of the device. Therefore, based on the identical indications, similar technological characteristics, and results of performance testing, TrackX is substantially equivalent to the submitter's own cleared device K173736.

7. PERFORMANCE DATA

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

Biocompatibility

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

Sterilization

Like the predicate device, the only sterile components are the TrackX Snaps that are attached to the instrument. 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}.

Shelf Life

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.

Electrical Safety and electromagnetic compatibility (EMC)

Not applicable. The subject device is a software-only device. It contains no electric components, generates no electrical emissions, and uses no electrical energy of any type.

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 provide a measurement off a reference point in the X-ray image. The location of projected markers should be within a 2mm mean of their expected 10mm increment from the detected instrument tip to each consecutive projected marker. The testing demonstrated that TrackX met specifications. The testing used established test methods that were used for the predicate device.

Software Verification

The purpose of this testing is to implement the intended changes for both the projection feature and the home base selector. The software testing performed for the modifications that are the subject of this Special 510(k) used established test methods that were used for the predicate device.

Animal Study

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

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 v. 2.0 is substantially equivalent to the TrackX as cleared in K173736.