July 28, 2022

Xoran Technologies LLC
% Mark McGarrow
VP of Quality and Operations
5210 S. State Rd.
Ann Arbor MI 48108

Re: K221230
Trade/Device Name: TRON
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, OXO, JAK
Dated: April 28, 2022
Received: April 29, 2022

Dear Mark Mcgarrow:

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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221230

Device Name

TRON

Indications for Use *(Describe)*

TRON is a mobile X-Ray imaging system with fluoroscopy and tomography capability that is intended to be used for anatomy that can safely fit within the device gantry and positioned within the imaging aperture (such as the head, neck, chest, abdomen, and extremities: arm, wrist, hand, leg, knee, ankle, and foot).

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.

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510(k) Number: K221230

This 510(k) summary of the Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

Date Prepared: April 22, 2022

Submitter:

Xoran Technologies LLC
5210 S. State Road
Ann Arbor, MI 48108

Contact Person:

Mark McGarrow
Vice President of Quality and Operations
Phone: 734-418-5125
Email: mark.mcgarrow@xorantech.com

Device Name and Classification:

Trade Name:	TRON
Classification Name:	Interventional Fluoroscopic X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR 892.1650
Regulation Name:	Image-intensified fluoroscopic x-ray system
Device Class:	Class II
Product Code:	OWB
Secondary Product Codes:	OXO, JAK

Predicate Device:

Trade Name:	Medtronic O-arm™ 02 Imaging System
510(k) number:	K200074 cleared 04/24/2020
Manufacturer:	Medtronic, Inc.
Classification Name:	Interventional Fluoroscopic X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR 892.1650
Regulation Name:	Image-intensified fluoroscopic x-ray system
Device Class:	Class II
Product Code:	OWB
Secondary Product Codes:	JAA, OXO

Reference Device:

Trade Name:	xCAT; xCAT for Neuro
510(k) number:	K061834 cleared 08/07/2006
Manufacturer:	Xoran Technologies LLC
Classification Name:	System, X-Ray, Tomography, Computed
Classification Panel:	Radiology
Classification Regulation:	21 CFR 892.1750
Regulation Name:	Computed tomography x-ray system
Device Class:	Class II
Product Code:	JAK

Device Description:

The TRON is a mobile fluoroscopy and cone-beam CT x-ray system for point-of-care (POC) imaging. The TRON system consists of a high voltage x-ray generator, 360-degree rotational open-bore gantry, x-ray tube assembly, x-ray controller, detector panel, and x-ray controls containing a power distribution unit, onboard PC and operator PC (user interface).

Indications for Use:

TRON is a mobile X-Ray imaging system with fluoroscopy and tomography capability that is intended to be used for anatomy that can safely fit within the device gantry and positioned within the imaging aperture (such as the head, neck, chest, abdomen, and extremities: arm, wrist, hand, leg, knee, ankle, and foot).

Substantial Equivalence:

TRON is substantially equivalent to the Medtronic O-arm™ 02 Imaging System in Indications for Use, hardware and technology. TRON is also substantially equivalent to the Xoran Technologies xCAT in technology, including both hardware and software. See comparison Table 1 and Table 2 below

Table 1 – Predicate Comparison

	Predicate Device: O-arm 02 Imaging System	Subject Device: TRON	Discussion
Classification	Class II	Class II	Identical
Product Code	OWB	OWB	Identical
Indications for Use	The O-arm O2 Imaging System is a mobile x-ray system designed for 2D and 3D imaging for adult and pediatric patients weighing 60lbs or greater and having an abdominal thickness greater than 16cm and is intended to be used where a physician benefits from 2D and 3D information of anatomic structures and objects with high x-ray attenuation such as bony anatomy and metallic objects. The O-arm O2 Imaging System is compatible with certain image guided surgery systems.	TRON is a mobile X-Ray imaging system with fluoroscopy and tomography capability that is intended to be used for anatomy that can safely fit within the device gantry and positioned within the imaging aperture (such as the head, neck, chest, abdomen, and extremities: arm, wrist, hand, leg, knee, ankle, and foot).	Equivalent
Cone Beam CT	The O-arm O2 Imaging System is a mobile cone-beam x-ray system with isocentric motion options. It allows 3D image reconstruction using a 360-degree rotation of the x-ray source and detector within closed gantry.	The TRON is a mobile cone-beam x-ray system with isocentric motion options. It allows 3D image reconstruction using a 360-degree rotation of the x-ray source and detector.	Equivalent
Detector Technology	40 x 30 cm (RoHS compliant, Flat-Panel Detector using a CsI scintillation)	40 x 30 cm (RoHS compliant, Flat-Panel Detector using a CsI scintillation)	Identical
X-ray Generator Technology	32 kW generator	1.050 kw generator	Equivalent in functionality

	Predicate Device: O-arm 02 Imaging System	Subject Device: TRON	Discussion
Collimator	Includes collimator assembly	Xoran designed beam limiter board 15006	Functional Equivalent
2D Imaging	2D Fluoroscopic	2D Fluoroscopic	Identical
3D Imaging	20cm and 40cm FOV	22cm FOV	Equivalent
Annotation	Allows for adding arrows lines and text to 2D images Additional annotation capability to perform angular measurements onto a 2D images. These measurements include closed, open and Cobb angles. It also provides the ability to place a right angle on the image	While using the MPR viewer: Allows for adding arrows lines and text to 2D images Additional annotation capability to perform angular measurements onto a 2D images. These measurements include closed, open and Cobb angles. It also provides the ability to place a right angle on the image	Equivalent
Image Transfer	Automatically transfers auto-registered navigation scans. Easy Image Transfer: Depending upon the clinical application and workflow within the procedure, this will automatically transfer non-auto-registered (non-navigated) images to the navigation system	Easy Image Transfer: Depending upon the clinical application and workflow within the procedure. Including being able to manually or automatically transfer images to navigation systems or PACs as needed.	Equivalent
3D Visualization (Enhanced Dynamic Range)	3D visualization of CBCT image on the MVS. It allows the user to window level the images as well as render oblique views Improved visualization of images that contain objects of high-x-ray attenuation such as metal implants on the Mobile View Station.	3D visualization of CBCT image on the workstation. It allows the user to window level the images as well as render oblique views.	Equivalent

	Predicate Device: O-arm 02 Imaging System	Subject Device: TRON	Discussion
Cybersecurity	Industry standard protocols with error detection for data transmission and storage. Authentication that includes usernames and passcodes Software integrity check	Industry standard protocols with error detection for data transmission and storage. Authentication that includes usernames and passcodes Software integrity check	Equivalent
Mobility	Moves fluidly in your OR; Inter-room mobility for concurrent cases	Can be easily moved from room to room and positioned for scanning by one person.	Equivalent

510(k) Summary

Table 2 – Reference Device

	Reference Device: xCAT	Subject Device: TRON	Discussion
Classification	Class II	Class II	Identical
Product Codes	JAK	OWB, OXO, JAK	JAK is Identical
Indications for Use	The xCAT is intended to be used for x-ray computed tomography imaging of anatomy that safely fits into the imaging gantry (such as the head, neck, wrist, ankle, hand, and foot).	TRON is a mobile X-Ray imaging system with fluoroscopy and tomography capability that is intended to be used for anatomy that can safely fit within the device gantry and positioned within the imaging aperture (such as the head, neck, chest, abdomen, and extremities: arm, wrist, hand, leg, knee, ankle, and foot).	Identical with the exception that TRON can also do fluoroscopy.
Detector Technology	40 x 30 cm (RoHS compliant, Flat-Panel Detector using a CsI scintillation)	40 x 30 cm (RoHS compliant, Flat-Panel Detector using a CsI scintillation)	Identical
X-ray Generator Technology	1.050 kw generator	1.050 kw generator	Identical
Collimator	Xoran designed beam limiter board 15006	Xoran designed beam limiter board 15006	Identical
2D Imaging	2D Radiography	2D Fluoroscopic	Identical with the exception that TRON can also do fluoroscopy.

	Reference Device: xCAT	Subject Device: TRON	Discussion
3D Imaging	A series of 360 deg projection data is collected and processed using sophisticated algorithms to generate a 3D volumetric data (reconstructed data), commonly referred to as computed tomography (CT).	A series of 360 deg projection data is collected and processed using sophisticated algorithms to generate a 3D volumetric data (reconstructed data), commonly referred to as computed tomography (CT).	Identical
Annotation	While using the MPR viewer: Allows for adding arrows lines and text to 2D images Additional annotation capability to perform angular measurements onto a 2D images. These measurements include closed, open and Cobb angles. It also provides the ability to place a right angle on the image	While using the MPR viewer: Allows for adding arrows lines and text to 2D images Additional annotation capability to perform angular measurements onto a 2D images. These measurements include closed, open and Cobb angles. It also provides the ability to place a right angle on the image	Identical
Image Transfer	Easy Image Transfer: Depending upon the clinical application and workflow within the procedure. Including being able to manually or automatically transfer images to navigation systems or PACs as needed.	Easy Image Transfer: Depending upon the clinical application and workflow within the procedure. Including being able to manually or automatically transfer images to navigation systems or PACs as needed.	Identical
3D Visualization (Enhanced Dynamic Range)	3D visualization of CBCT image on the workstation. It allows the user to window level the images as well as render oblique views.	3D visualization of CBCT image on the workstation. It allows the user to window level the images as well as render oblique views.	Identical

	Reference Device: xCAT	Subject Device: TRON	Discussion
Cybersecurity	Industry standard protocols with error detection for data transmission and storage. Authentication that includes usernames and passcodes Software integrity check	Industry standard protocols with error detection for data transmission and storage. Authentication that includes usernames and passcodes Software integrity check	Identical
Mobility	Can be easily moved from room to room and positioned for scanning by one person.	Can be easily moved from room to room and positioned for scanning by one person.	Identical

Comparison of Technological Characteristics:

The substantial equivalence of TRON with the predicate and reference devices are presented in the chart above and have the following overall shared technological characteristics:

Mobile Imaging: Wheeled configuration for point-of-care (POC) x-ray imaging.

All three devices are meant to be rolled to the patient location to perform x-ray imaging techniques for immediate image viewing at the POC.

Image Acquisition: Cone-beam x-ray configuration with flat panel detector.

All three devices use equivalent/identical components for x-ray imaging.

Imaging Bore: Gantry configuration with 360deg rotation.

All three device are configured to enable alignment for full rotation of the x-ray source and detector panel around the patient targeted anatomy.

Patient Support/Positioning: Used with standard patient supports.

All three devices are meant to be used with x-ray imaging compatible patient support tables/surfaces typically found in the hospital operating room setting. All three devices use on-board lasers to guide patient positioning of the targeted anatomy.

The detailed properties of the subject device (TRON) presented in the comparison tables above (see Table 1 and Table 2), and described throughout this submission, do not differ significantly from the legally marketed predicate device with regards to fundamental scientific technology, nor do they reflect a significant change in the indications for use. The differences between the subject device and the legally marketed predicate device have been assessed using Risk Management. The results of these efforts demonstrate that the device is as safe and effective as

the predicate device and does not raise different questions of safety and effectiveness than the predicate.

Performance Testing:

TRON has undergone Bench Testing, SW Validation, and Product Validation testing to demonstrate its safety, effectiveness, and conformance to its user needs, indications for use, as required by 21 CFR 820.30 Design controls – (f) Design Verification, and (g) Design Validation.

The device testing has followed the same process and it has been documented in the manner listed below:

- The test plan and test instructions were laid out in the Test Protocol and Test Cases documents, where information such as test configurations, test sample sizes, and test result evaluation criteria, is established.
- The testing was performed, and the results were captured in the Test Results document.
- The testing was performed on production equivalent units. Tests were performed by qualified Xoran personnel, familiar with the function and use of TRON, but not directly responsible for its design.
- The evaluation of the results and of the overall test result was discussed in the Test Report document
- Identified hazards and risks were tested and successfully mitigated by traceable requirements.

TRON meets all the evaluation criteria for Bench Testing, SW Validation, and Product Validation tests

Performance Testing - Animal

N/A – No animal testing was conducted for the TRON

Performance Testing - Clinical

N/A – No clinical testing was conducted for the TRON

Conformance with IEC Standards

TRON has been designed to comply with the following standards:

- EN 60601-1:2005
- EN 60601-1-2:2015
- EN 60601-1-3:2008

- IEC 60601-2-44:2009

Guidance Documents and Resources

TRON has been designed utilizing the following FDA Guidance Documents:

- Medical X-Ray Imaging Devices Conformance with IEC Standards
- Pediatric Information for X-ray Imaging Device Premarket Notifications
- Guidance for Submission of 510(k)s for Solids State X-ray Imaging Devices
- Information to Support a claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices
- The Image Gently Alliance – Link: http://www.imagegently.org
- FDA Pediatric X-ray Imaging – Link: https://www.fda.gov/radiation-emitting-products/medical-imaging/pediatric-x-ray-imaging

Conclusion

The TRON is intended for the same indications for use as the Medtronic O-arm™ 02 Imaging System. It uses components similar to those in the Medtronic O-arm™ 02 Imaging System (e.g. x-ray tube, collimator, x-ray generator, operator console). It is Xoran Technologies, LLC's opinion that the TRON is substantially equivalent to the cleared predicate device, the Medtronic O-arm™ 02 Imaging System