Medtronic, Inc.
% Mr. Dean Honkonen
Sr. Regulatory Affairs Manager
300 Foster Street
LITTLETON MA 01460

April 24, 2020

Re: K200074
Trade/Device Name: Medtronic O-arm™ O2 Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA, OXO
Dated: March 27, 2020
Received: March 30, 2020

Dear Mr. Honkonen:

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)*
K200074

Device Name
Medtronic O-arm™ O2 Imaging System

Indications for Use *(Describe)*
The O-arm O2 Imaging System is a mobile x-ray system designed for 2D and 3D imaging for adults 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 anatomical structures and objects with high x-ray attenuation such as bony anatomy and metallic objects.

The O-arm O2 Imaging System in compatible with certain image guided surgery systems.

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.

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510(k) Summary

Submitter: Medtronic Navigation, Inc. (Littleton)
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Date Summary Prepared: January 13, 2020

Device Trade Name: Medtronic O-arm™ O2 Imaging System

Common Name: Interventional Fluoroscopic X-ray System

Device Classification: Class II

Product Code: Primary OWB
Secondary OXO, JAA

Classification Name: 892.1650 - Image Intensified Fluoroscopic X-ray System, Mobile

Predicate Device: K173664 – O-arm™ O2 Imaging System 4.1.0 software

Device Description:

The O-arm™ O2 Imaging System is a mobile x-ray system that provides 3D and 2D imaging. O-arm O2™ Imaging System was originally cleared for market under the original 510(k) K151000 and subsequently via special 510(k) K173664. The device is classified under primary product code OWB (secondary product codes OXO, JAA) ref 21 CFR 892.1650.

Modified Device:

This submission for the O-arm™ O2 Imaging System 4.2.0 software release introduces following features:

- "2D Long Film" Imaging Protocol (Intraoperative Radiographic Scan)
- Gantry Rotor Angle and Tilt Angle Display
- User Access Enhancements

These features are described in more detail in the Substantial Equivalence section.

The O-arm™ O2 Imaging System consists of two main assemblies that are used together:

- The Image Acquisition System (IAS)
- The Mobile View Station (MVS)

The two units are interconnected by a single cable that provides power and signal data. The IAS has an internal battery pack that provides power for motorized transportation and gantry positioning. In addition, the battery pack is used to power the X-ray tank. The MVS has an internal UPS to support its function when mains power is disconnected.

The O-arm™ O2 Imaging System operates off standard line voltage within the following voltages:

- VAC 100, 120 or 240
- Frequency 60Hz or 50Hz
- Power Requirements 1440 VA

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.

Substantial Equivalence:

O-arm™ O2 Imaging System with 4.2.0 software is substantially equivalent to the following device:

K173664 – O-arm™ O2 Imaging System 4.1.0 software

The unmodified device (predicate - K173664) and the modified device are compared in table below:

Device Comparison Table

	Predicate Device	**Modified Device**	**Discussion**
	O-arm O2 Imaging System K173664	**With revision 4.2.0 software**	
Classification	Class II	Class II	Identical
Product Code	OWB; 892.1650	OWB; 892.1650	Identical
Indications for Use	The O-arm O2 Imaging System is a mobile x-ray system designed for 2D fluoroscopic 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.	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.	Changed to remove the word "fluoroscopic". O-arm O2 Imaging System 4.2.0 software uses more than one 2D mode. Modes of operation are described in the Instructions for Use.
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 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.	Identical

	Predicate Device	**Modified Device**	**Discussion**
	O-arm O2 Imaging System K173664	**With revision 4.2.0 software**	
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
Generator Technology	32 kW, RoHS compliant generator	32 kW, RoHS compliant generator	Identical
2D Imaging	2D Fluoroscopic	2D Fluoroscopic	Identical
2D Imaging	Manually stitched fluoroscopy	**Added Feature:** Automatically stitched 2D Radiographic (Long Film)	**Added Feature:** The O-arm O2 2D Long Film feature leverages the motion capability of the O-arm to provide an imaging mode, whereby 2D narrowly collimated projection images would be automatically acquired while the gantry is moving from two preprogramed gantry locations. These projections would then be automatically stitched together using knowledge of the motion profile to form a single 2D Long Film.
3D Imaging (20 cm FOV)	Full Fan (20cm FOV) scan acquisition	Full Fan (20cm FOV) scan acquisition	Identical

	Predicate Device O-arm O2 Imaging System K173664	Modified Device With revision 4.2.0 software	Discussion
3D Imaging Protocols (20 cm FOV)	Available presets: Standard 3D HD3D (High Definition) Enhanced Cranial Low Dose 3D	Available presets: Standard 3D HD3D (High Definition) Enhanced Cranial Low Dose 3D	Identical
3D Imaging (40 cm FOV)	Half-fan single scan acquisition	Half-fan single scan acquisition	Identical
3D Imaging Protocols (40 cm FOV)	Available presets: HD3D (high definition) equivalent to 750 projections Stereotaxy protocols	Available presets: HD3D (high definition) equivalent to 750 projections Stereotaxy protocols	Identical
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.	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.	Changed to accommodate the larger image size of 2D Radiographic (Long Film).

	Predicate Device	Modified Device	Discussion
	O-arm O2 Imaging System K173664	**With revision 4.2.0 software**	
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	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	Identical
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 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.	Identical

Cybersecurity	Industry standard protocols with error detection for data transmission and storage. Authentication that includes user names and passcodes Software integrity check	**Added Feature:** Enhanced user access	**Added Feature** • The ability to have a user log in to the O-arm system through the Lightweight Directory Access Protocol (LDAP) by using hospital domain credentials set up by hospital IT. • The ability for the hospital IT team to configure group policies on their hospital IT systems and assign the proper user group to individuals with O-arm user and/or O-arm hospital administrator privileges. • The ability to maintain legacy O-arm O2 4.1.0 local authentication methods if customers prefer this method over LDAP. • The ability for Medtronic Service or Manufacturing to configure the authentication feature based on customer requests. • The ability for Authorized personnel to audit changes made within the system related to Protected Health Information (PHI), User Management and System Configuration. • Encryption of PHI information stored on MVS computer for easier integration of the improved User Access Enhancements into various Hospital IT systems.

	Predicate Device O-arm O2 Imaging System K173664	Modified Device With revision 4.2.0 software	Discussion
Hardware – Collimator Assembly	No slot filter present in Collimator Assembly	**Changed hardware** Collimator Assembly includes a slot filter for 2D Long Film Imaging	**Changed hardware** Collimator Assembly includes a slot filter for 2D Long Film Imaging capability. New filter ladder assembly designed for 2D Long Film allows for higher repeatability of filter positioning than the current design.
Software - Gantry Tilt & Rotor Angle Display	Not present	**Added Feature** Display of the Gantry Rotor Angle and Gantry Tilt Angle on the Pendant	**Added feature:** Gantry Tilt & Rotor Angle Display will provide following capability: • Will enable users to view the tilt angles of the gantry from the O-arm pendant. • Will enable users to view the relative angle/location of X-ray source & detector.

Performance Testing:

Testing conducted demonstrates the product will perform as intended according to the outlined design requirements. The following testing was conducted on the O-arm™ O2 Imaging System device to establish substantial equivalence with the predicate device and verify that device will perform as intended in meeting all the design inputs:

- AAMI/ANSI ES 60601-1 2005+A1:2012 - Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2:2014 - Medical Electrical Equipment – Part 1-2: General requirements for safety; Electromagnetic Compatibility – Requirements and Tests
- IEC 60601-1-3:2008 + A1:2013 - Medical Electrical Equipment – Part 1-3: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Radiation Protection in Diagnostic X-ray Equipment
- IEC 60601-2-28:2010 – Medical electrical equipment part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
- IEC 60601-2-43:2010 + A1:2017 – Medical electrical equipment Part 2-43: Particular requirements for the basic safety and essential
- IEC60601-1-6:2010 + A1:2013 - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- Software Verification and Validation testing verifying the software requirements perform as intended.
- Hardware verification ensuring the hardware requirements identified for the system perform as intended.
- The Dosimetry Report documents the dosimetry measurements for the various modes of the O-arm™ O2 Imaging System with 4.2.0 software.
- Usability Testing was conducted according to the FDA guidance *Applying Human Factors and Usability to Optimize Medical Device Design*. Users conducted a series of imaging functions under simulated use conditions.
- The Image Quality Assessment of the O-arm™ O2 Imaging System provides a quantitative image quality assessment of the O-arm O2 Imaging System with 4.2.0 in comparison to the predicate O-arm™ O2 Imaging System with 4.1.0.
- The O-arm™ Cadaver Image Pair Study evaluated the clinical utility of the images obtained using the O-arm™ O2 Imaging System with 4.2.0 compared to the images obtained using the predicate O-arm™ O2 Imaging System with 4.1.0.

Conclusion:

The O-arm™ O2 Imaging System with 4.2.0 software is similar in technological characteristics, imaging performance and indications for use as the predicate device listed. These aspects, along with the functional testing conducted to the FDA recognized standards, demonstrate that O-arm™ O2 Imaging System with 4.2.0 software does not raise new risks of safety and effectiveness when compared to the predicate.