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

December 29, 2017

Re: K173664
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: II
Product Code: OWB, OXO, JAA,
Dated: November 28, 2017
Received: November 29, 2017

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. 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)*

K173664

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 fluoroscopic and 3D imaging for adult and pediatric patients weighing 60 lbs 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.

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) 300 Foster Street Littleton, MA 01460
Contact Person:	Dean Honkonen Regulatory Affairs Manager Phone: (978)698-6065 Fax: (978)698-6090 E-mail: dean.honkonen@medtronic.com

Date Summary Prepared:	October 11, 2017
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
Predicate Device:	K151000 – Medtronic O-arm O2 Imaging System

Device Description:
The O-arm O2 Imaging System is a mobile x-ray system that provides 3D imaging as well as 2D fluoroscopic imaging. It was originally cleared for market under 510(k) K151000. The device is classified under primary product code OWB (secondary product codes OXO, JAA) ref 21 CFR 892.1650.

Modified Device:
This is a special submission for the addition of the following software features:

- Angular Annotation
- Easy Image Transfer
- Enhance Dynamic Range
- Cybersecurity Enhancements

These changes are only changes in software. There are no changes related to radiation performance. There are no changes to the device hardware required for these software changes. These features are described in more detail below and in the Device Description. This software also includes defect corrections.

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 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 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.

Substantial Equivalence:
O-arm O2 with revision 4.1.0 software is viewed as substantially equivalent to the unmodified device as there are no changes that impact indications for use or fundamental technology. We have compared the unmodified device (predicate) and the modified device in Table 5-1 below:

Table 5-1: Device Comparison Table

	Predicate	Modified Device	Discussion
	O-arm O2 Imaging System	**O-arm O2 Imaging System** **With revision 4.1 Software**	
Classification	Class 2	Class 2	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 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.	Identical

	Predicate	Modified Device	Discussion
	O-arm O2 Imaging System	**O-arm O2 Imaging System** **With revision 4.1 Software**	
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
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 with improved electrical interface.	32 kW, RoHS compliant generator with improved electrical interface.	Identical
2D Imaging	2D Fluoroscopic	2D Fluoroscopic	Identical
3D Imaging (20 cm FOV)	Full Fan (20cm FOV) scan acquisition	Full Fan (20cm FOV) scan acquisition	Identical
3D Imaging Protocols (20 cm FOV)	Available presets: 1. Standard 3D 2. HD3D (High Definition) 3. Enhanced Cranial 4. Low Dose 3D	Available presets: 5. Standard 3D 6. HD3D (High Definition) 7. Enhanced Cranial 8. Low Dose 3D	Identical
3D Imaging (40 cm FOV)	Half-fan single scan acquisition	Half-fan single scan acquisition	Identical

	Predicate	Modified Device	Discussion
	O-arm O2 Imaging System	**O-arm O2 Imaging System** **With revision 4.1 Software**	
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	Allows for adding arrows lines and text to 2D images **Added:** 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.	Additional functionality
Image Transfer	Allows for transfer of data to external devices.	Automatically transfers auto-registered navigation scans. **Added:** Depending upon the clinical application and workflow within the procedure, this will automatically transfer non-auto-registered (non-navigated) images to the navigation system	Improves workflow The capability to transfer non-auto-registered (non-navigated) images to the navigation system existed in 510(k) K15000 but required several manual steps

	Predicate	Modified Device	Discussion
	O-arm O2 Imaging System	**O-arm O2 Imaging System** **With revision 4.1 Software**	
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	3D visualization of CBCT image on the MVS. It allows the user to window level the images as well as render oblique views **Added:** Improved visualization of images that contain objects of high-x-ray attenuation such as metal implants on the Mobile View Station.	Improved visualization capability
Cybersecurity	Hardcoded passcodes for system access Industry standard protocols with error detection for data transmission and storage.	Industry standard protocols with error detection for data transmission and storage. **Removed** hardcoded passwords **Added:** Authentication that includes user names and passcodes Software integrity check	Increased cybersecurity protection.

Performance Testing:
Testing conducted demonstrates the product will perform as intended according to the outlined design requirements. The following testing was conducted in accordance to the following FDA recognized standards:

- AAMI/ANSI ES 60601-1:2012 - Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)

- IEC 60601-1-2:2007 - Medical Electrical Equipment – Part 1-2: General requirements for safety; Electromagnetic Compatibility – Requirements and Tests (2/2014)

- IEC 60601-1-3:2008 - Medical Electrical Equipment – Part 1-3:General Requirements for Basic Safety and Essential Performance – Collateral Standard: Radiation Protection in Diagnostic X-ray Equipment (1/2014)

- 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 (8/2013)

- IEC 60601-2-43:2010 – Medical electrical equipment Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures (3/2010)

As required in Special 510(k) submissions Medtronic Navigation Inc. (Littleton) performed a Risk / Hazard Analysis in accordance to company procedures which was used to assess the impact of the modifications listed above.

Based on the Risk / Hazard Analysis an identification of the verification and / or, validation activities required was made and appropriate methods or tests and the applicable pass / fail criteria applied were performed.

The following guidance documents used in the development of O-arm O2 Imaging System:

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

- Off-The-Shelf Software Use in Medical Devices

Conclusion:
The O-arm O2 Imaging system is similar in technological characteristics, imaging performance and indications for use as the predicate devices listed. These aspects, along with the functional testing conducted to the FDA recognized standards, demonstrate that O-arm O2 Imaging System with 4.1 software does not raise new risks of safety and effectiveness when compared to the predicates.