DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 6, 2015

Medtronic, Inc.
Medtronic Navigation, Inc. (Littleton)
% Mr. Rishi Sinha
Prinicipal Regulatory Affairs Specialist
300 Foster Street
LITTLETON MA 01460

Re: K151000
Trade/Device Name: 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 and JAA
Dated: June 30, 2015
Received: July 2, 2015

Dear Mr. Sinha:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
~~N/A~~ K151000

Device Name
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:	Rishi Sinha (Primary) Principal Regulatory Affairs Specialist Phone: (269) 903-4373 Fax: (269) 353-5924 E-mail: rishi.k.sinha@medtronic.com Paul Smolenski (Alternate) Senior Regulatory Affairs Manager Phone: (978)698-6065 Fax: (978)698-6090 E-mail: paul.d.smolenski@medtronic.com
Date Summary Prepared:	June 30th, 2015
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:	K092564 – Medtronic O-arm® 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 in 2005 via K050996. Additional submissions were made in 2006 (K060344) and 2009 (K092564). The device is classified under primary product code OWB (secondary OXO, JAA) , ref 21 CFR 892.1650. O-arm® O2 Imaging System, also referred to as "O-arm® O2", adds an extended field of view imaging mode that offers twice the lateral field of view as the prior design to provide clinicians further visualization options in larger anatomic regions and anatomical structures. It accomplishes this task with essentially the same hardware design as described within. The system consists of two parts: the O-arm® Image Acquisition System (IAS), comprising of a x-ray generator, amorphous silicon flat panel x-ray detector and the x-ray control user interface and the Mobile View Station (MVS), comprising of the image processors, a user interface for image and patient handling and viewing monitor. The O-arm® O2 Imaging System consists of two main assemblies that are used together during fluoroscopic imaging: • 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 O-arm® 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® operates off standard line voltage within the following voltages:

- VAC 100, 120 or 240
- Frequency 60Hz; 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 is substantially equivalent to the following device:

- K092564 – O-arm® Imaging System

Table 1: O-arm® O2 Predicate Device Comparison Table

	Subject Device	**Predicate**
	O-arm® O2 Imaging System	**O-Arm® 1000 Imaging System (K092564)**
Classification	Class 2	Class 2
Product Code	OXO; 892.1650	OXO; 892.1650
Indications for Use	The O-arm® O2 Imaging System is a mobile x-ray system designed for 2D fluoroscopic and 3D imaging 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® Imaging System is compatible with certain Image Guided Surgery Systems.	The O-arm® Imaging System is a mobile x-ray system designed for 2D fluoroscopic and 3D imaging 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® Imaging System is compatible with certain Image Guided Surgery systems.

	Subject Device	Predicate
	O-arm® O2 Imaging System	**O-Arm® 1000 Imaging System (K092564)**
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® 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.
Detector Technology	40 x 30 cm (RoHS compliant, Flat-Panel Detector using a CsI scintillation)	40 x 30 cm (Flat-Panel Detector using a CsI scintillation)
Generator Technology	32 kW, RoHS compliant generator with improved electrical interface.	32kW Generator
2D Imaging	2D Fluoroscopic	2D Fluoroscopic
3D Imaging (20 cm FOV)	Full Fan (20cm FOV) scan acquisition	Full Fan (20cm FOV) scan acquisition
3D Imaging Protocols (20 cm FOV)	Available presets: 1. Standard 3D 2. HD3D (High Definition) 3. Enhanced Cranial 4. Low Dose 3D	Available presets: 1. Standard 3D 2. HD3D (High Definition) 3. Enhanced Cranial
3D Imaging (40 cm FOV)	Half-fan single scan acquisition	No 3D Imaging at 40cm FOV
3D Imaging Protocols (40 cm FOV)	Available presets: 1. HD3D (high definition) equivalent to 750 projections	No 3D Imaging at 40cm FOV

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 of the O-arm O2 Imaging System and verify that device will perform as intended meeting all of the design inputs.

- 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)
- 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 Dose Setting Guidance for Extra-small Patient Size determines recommended dose settings (kVp/mA pairs) for an extra-small patient population to help the end user when imaging such patients.
- The Image Quality Assessment of the O-arm® O2 System provides a quantitative image quality assessment of the O-arm® O2 system in comparison to the predicate O-arm® 1000 device.
- The Dosimetry Report documents the dosimetry measurements for the various modes of the O-arm O2 System.
- The 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 O-arm® Cadaver Image Pair Study evaluates the clinical utility of the images obtained using the O-arm® O2 Imaging System compared to the images obtained using the predicate O-arm® 1000 and the reference Artis Zeego device.

All performance testing was conducted to ensure the product meets all prescribed design inputs.

Conclusion: The O-arm® O2 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 does not raise new risks of safety and effectiveness when compared to the predicates.