June 21, 2024

Medtronic Navigation, Inc
℅ Anamika Patel
Senior Regulatory Affairs Specialist
200 Beaver Brook Rd
BOXBOROUGH, MA 01719

Re: K240465
Trade/Device Name: 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, OXO, JAA
Dated: February 16, 2024
Received: May 23, 2024

Dear Anamika Patel:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240465

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 and 3D imaging for adult and pediatric patients weighing 60 lbs or greater and having an abdominal thickness greater than 16 cm, 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

I. **Company:**

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II. **Date Summary Prepared:** February 16, 2024

III. **Device Trade Name:** O-arm™ O2 Imaging System

Common Name: Interventional Fluoroscopic X-ray System

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

IV. **Device Classification:** Class II

V. **Product Code:** Primary - OWB
Secondary - OXO, JAA

VI. **Predicate Device:** K200074 – O-arm™ O2 Imaging System 4.2.0 software

VII. **Product 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 and traditional 510(k) K200074. The device is classified under primary product code OWB (secondary product codes OXO, JAA) Regulation 21 CFR 892.1650.

VIII. **Modified Device**: O-arm™ O2 Imaging System with 4.3.0 software.

This submission for the O-arm™ O2 Imaging System 4.3.0 software release introduces the following features:

- Medtronic Implant Resolution (MIR)
- 3D Long Scan (3DLS)
- Spine Smart Dose (SSD)

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

IX. 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.

X. Substantial Equivalence:

O-arm™ O2 Imaging System with 4.3.0 software is substantially equivalent to the following device: K200074 – O-arm™ O2 Imaging System 4.2.0 software.

The unmodified device (predicate – K200074) and the modified device are compared in table below:

Comparison of the Technological Characteristics

Feature/ Attribute	Subject Device O-arm O2 Imaging System 4.3.0 Software	Predicate O-arm O2 Imaging System 4.2.0 Software	Discussion
Classification	Class II	Class II	Identical
Product Code	OWB, OXO and JAA	OWB, OXO and JAA	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.	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.	Identical
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

Feature/ Attribute	Subject Device O-arm O2 Imaging System 4.3.0 Software	Predicate O-arm O2 Imaging System 4.2.0 Software	Discussion
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
2D Imaging	Automatically stitched 2D Radiographic (Long Film)	Automatically stitched 2D Radiographic (Long Film)	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 5. SpineSmart Dose	Available presets: 1. Standard 3D 2. HD3D (High Definition) 3. Enhanced Cranial 4. Low Dose 3D	Added new preset called SpineSmart Dose (See below for details) in our subject device
3D Imaging (40 cm FOV)	Half-fan single scan acquisition	Half-fan single scan acquisition	Identical
3D Imaging Protocols (40 cm FOV)	Available presets: 1. HD3D (high definition) equivalent to 750 projections	Available presets: 1. HD3D (high definition) equivalent to 750 projections	Identical
System Software	Version 4.3.0	Version 4.2.0	Equivalent, with the addition of 4.3.0 features (KCMAR, SSD and 3DLS) described in Section 3 Device Description.
Known Component Metal Artifact Reduction ("KCMAR")/Medtronic Artifact Reduction (MAR)/ Medtronic Implant Resolution (MIR)	The Medtronic Implant Resolution System feature provides enhanced visualization of supported Medtronic implants by reducing artifacts generated by imaging hardware, such as screws and spinal implants, and enhancing hardware visibility.	The current system is used for imaging screws and implants, however, it does not have the feature to reduce artifacts generated by imaging hardware, such as screws and spinal implants.	**Added Feature:** Known-Component Metal Artifact Reduction (KCMAR) is a specialized algorithm, which suppresses this metal artifact on pedicle screws using the "known" geometry of those screws.

Feature/ Attribute	Subject Device O-arm O2 Imaging System 4.3.0 Software	Predicate O-arm O2 Imaging System 4.2.0 Software	Discussion
3D Long Scan Protocol	3D Long Scan The 3D Long Scan feature provides functionality to specify start and end positions for acquiring two to three (depending on length) auto-registered 3D scans in combination with the IGS system. The maximum achievable length for a 3D Long scan is approximately 43.8 cm (17.24 in).The minimum scan length for a 3D Long Scan is approximately 19.2 cm (7.6 in).	2D Long Film The 2D Long Film mode provides functionality for acquiring an intraoperative linear X-ray scan. In this mode, the O-arm™ O2 Imaging System scans while the gantry moves left/right along the z-axis during acquisition between the positions stored in memory presets 1 and 2. When the saved memory presets are stored at the extremes of the z-axis, the maximum length and width of a 2D Long Film image is 47 cm by 20 cm at isocenter.	**Added Feature:** 3D Long Scan is the combination of automatic registration with navigation systems (e.g., Medtronic StealthStation), lateral access to the patient, and a navigated three-dimensional scan of 15-43cm of the patient's spine. 2D Long Film was validated and FDA-cleared previously.
SpineSmart Dose (SSD)	SpineSmart Dose SSD mode is designed to provide an additional preset setting for standard 3D acquisitions with a lower overall dose reduction of around 70% from the standard acquisition protocols, for spinal applications. The rotor spins at 30° per second, acquires images at 30 frames per second, and captures approximately 100 projections.	Normal dose In 3D acquisition modes, the O-arm™ O2 system IAS creates a series of pulsed x-ray exposures throughout a complete 360-degree rotation of the gantry rotor. The rotor spins at 30° per second, acquires images at 30 frames per second and captures approximately 391 projections.	**Added Feature:** Spine Smart Dose feature leverages Machine Learning technology with existing O-arm™ images to achieve reduction in dose on the O-arm™ O2 Imaging System. It is an algorithm designed to reduce the noise of 3D reconstructions acquired from fewer acquisitions so that clinically viable 3D images can be produced using fewer projections.

XI. **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.
- The Dosimetry Report documents the dosimetry measurements for the various modes of the O-arm™ O2 Imaging System with 4.3.0 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 O-arm™ Cadaver Image Pair Study evaluated the clinical utility of the images obtained using the O-arm™ O2 Imaging System with 4.3.0 compared to the images obtained using the predicate O-arm™ O2 Imaging System with 4.2.0.
- FDA guidance document "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."

Performance Testing Summary

Testing	Testing Methodology / Parameters	Overall Results
Spine Smart Dose Clinical Equivalence Design Validation	The Spine Smart Dose (SSD) feature uses a sparse image acquisition, an FDK reconstruction and a machine learning denoising algorithm to provide images of the spine at significantly lower dose (around 70% lower dose to patient). In a blinded review by board-certified neuroradiologist involving 100 clinical	This clinical and cadaver image pair validation study demonstrated that the clinical value of the O-arm O2 4.3 SSD images is clinically equivalent when compared to corresponding images from the Predicate Device (O-arm O2 4.2.0 Imaging System) under the specified indications.

	image pairs, O-arm™ O2 Imaging System 4.3.0 SSD images were deemed clinically equivalent to O-arm™ O2 Imaging System 4.2.x Standard and Predicate High-Definition modes. The dose of the SSD images reviewed in this study were approximately ¼ the dose of the corresponding Standard images.	
Spine Smart Dose Bench Testing	Phantom testing was performed on Spine Smart Dose feature to verify the system level requirements for Image Quality (3D Line pair, Contrast, MTF, Uniformity and Geometric accuracy) and Navigational accuracy in terms of millimeters.	All the bench testing demonstrated Spine Smart Dose met all the system level requirements.
KCMAR Clinical Equivalence Design Validation	The 3D O-arm acquisitions reconstructed using the predicate device without KCMAR feature and the same acquisitions reconstructed using the subject device with KCMAR feature were compared for their clinical equivalence. Board-certified radiologists provided clinical utility scores (1-5 scale) for the 40 image pairs from four cadavers acquired using Standard 3D imaging mode. The cadavers were of small, medium, large, and extra-large habitus. In the subsequent study, board-certified radiologists provided clinical utility scores for the 33 image pairs from two cadavers acquired using other 3D imaging modes (Low Dose, HD, and SSD). The cadavers were of small and extra-large habitus.	This cadaver image pair validation study demonstrated that the clinical value of the KCMAR image with the O-arm O2 Imaging System version 4.3.0 is statistically better when compared to corresponding images from the Predicate Device (O-arm O2 Imaging System version 4.2.0) under the specified indications.
KCMAR Bench Testing	Phantom studies were used to qualitatively compare the metal artifact reduction between non-KCMAR and KCMAR processed images with supported Medtronic implants. In addition, phantom studies were conducted to quantitatively assess the accuracy of the implant location in millimeters and degrees.	All the bench testing demonstrated KCMAR met all the system level requirements.
3D Long Scan Clinical Utility Validation	Board-certified radiologists provided clinical utility scores (1-5 scale) for Standard, Standard 3DLS, and SSD 3DLS acquisitions of three cadavers. The cadavers were of small, medium, and extra-	This cadaver clinical utility study demonstrated that the clinical utility of the Standard 3DLS and SSD 3DLS with the O-arm O2 Imaging System version 4.3.0 is statistically equivalent when compared to

	large habitus, and two of the cadavers were instrumented with pedicle screw hardware. Paired statistical equivalence testing of the clinical utility scores was performed between (1) the Standard (predicate) and Standard 3DLS mode, and (2) the Standard (predicate) and SSD 3DLS mode. Each test was performed on 45 paired samples.	the corresponding Standard acquisition mode that is available in the predicate system (version 4.2.0).
3D Long Scan Bench Testing	Phantom testing was performed on the 3D Long Scan feature to verify the system level requirements for Image Quality (3D Line pair, Contrast, MTF and Geometric accuracy) and Navigational accuracy in terms of millimeters.	All the bench testing demonstrated 3D Long Scan met all the system level requirements.
Usability	Usability for the 3DLS, SSD, and KCMAR features was assessed in multiple formative evaluations and tested in two summative validations with the clinically relevant users in simulated use environments. Summative validation of critical tasks and new workflows for 3DLS and SSD was conducted with surgeons, spine representatives, and radiation technologists. Summative validation of KCMAR critical tasks and new workflows was conducted with surgeons and spine representatives.	The 3DLS, SSD, and KCMAR features passed summative validation. Results of the summative validations provided objective evidence the O-arm O2 Imaging System with 4.3.0 software is safe and effective for the intended users, uses, and use environments.
Dosimetry	Dosimetry studies were used to confirm the dose accuracy (kV, mA, CTDI and DLP) for the new acquisition features including the Spine Smart Dose and 3D Long Scan.	All the dosimetry testing passed the system level requirements.

XII. **Conclusion**

The O-arm™ O2 Imaging System with 4.3.0 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 4.3.0 software does not raise new risks of safety and effectiveness when compared to the predicate.