December 22, 2025

OXOS Medical
℅ Jean-Marie Toher
Senior Regulatory Specialist
1100 Peachtree St. NE
Suite 700
ATLANTA, GA 30309

Re: K252068
Trade/Device Name: MC2 Portable X-ray System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, OXO, IZL
Dated: July 1, 2025
Received: November 24, 2025

Dear Jean-Marie Toher:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic 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)*
K252068

Device Name
MC2 Portable X-ray System

Indications for Use *(Describe)*
The MC2 Portable X-ray System is indicated for use by qualified/trained medical professionals on adult and pediatric patients for:
- Handheld orthopedic radiographic procedures of the extremities.
- Handheld orthopedic serial radiographic procedures of the extremities, excluding the shoulder, hip, and knee. Handheld serial radiographic imaging is limited to forward holding position only.
- Stand-mounted orthopedic radiographic, serial radiographic, fluoroscopic, and orthopedic interventional procedures of the extremities, inclusive of shoulders and knees.

The device is NOT intended for use during surgery. The device is NOT intended to replace a stationary radiographic or fluoroscopic system, which may be required for optimization of image quality and radiation exposure.

The device is to be used in healthcare facilities where qualified operators are present (e.g., outpatient clinics, urgent cares, imaging centers, sports medicine facilities, occupational medicine clinics).

The device is NOT intended to be used in environments with the following characteristics:
-Aseptic or sterile fields, such as in surgery
-Home or residential settings or other settings where qualified operators are not present
-Vehicular and moving environments
-Environments under direct sunlight
-Oxygen-rich environments, such as near an operating oxygenation concentrator

Contraindications
The MC2 System is contraindicated as follows:
The MC2 System is NOT intended for bariatric patients.
The MC2 System is NOT intended for mammography.
The MC2 System is NOT intended for dental applications.
The MC2 System is NOT intended to come in contact with non-intact skin.
The MC2 System is NOT intended for cardiac applications.
The MC2 System is NOT intended for use in proximity to pacemakers or implantable cardioverter-defibrillators (ICDs).

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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OXOS

510(k) Summary

Contact Details

	Applicant Information	Primary Correspondent Information
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Device Information

Device Information	
Trade Name	MC2 Portable X-ray System
Common Name	Image-intensified fluoroscopic x-ray system
Classification Name Regulation Number	Image-Intensified Fluoroscopic X-Ray System 21 CFR 892.1650
Product Codes	OWB, OXO, IZL

Legally Marketed Predicate Devices

Type	K-Number	Trade Name	Product Code
Predicate	K241567	MC2 Portable X-ray System	OWB, OXO, IZL
Reference	K212654	Micro C Medical Imaging System, M01	IZL
Reference	K211191	Virtual C DRF	OXO, OWB, JAA

Device Description Summary

The MC2 Portable X-ray System (“MC2 System” or “MC2”) is a portable and handheld X-ray system designed to aid clinicians with point-of-care visualization through diagnostic X-rays of the shoulders to fingertips and knees to toes. The device allows clinicians to select desired technique factors best suited for their patient's anatomy. The MC2 consists of two major system components: the emitter and the cassette. The MC2 emitter and cassette are battery-powered and are charged via a wired charger. The system is intended to interface wirelessly to an external tablet when used with the OXOS Device App or to a monitor with an off-the-shelf ELO Backpack and the OXOS Device App. The MC2 utilizes an Infrared Tracking System to allow the emitter to be positioned above the patient's anatomy and aligned to the cassette by the operator. The MC2 also utilizes a LIDAR system to ensure patient safety by maintaining a safe source-to-skin distance.

The MC2 is capable of three X-ray imaging modes: single radiography, serial radiography, and fluoroscopy. In single and serial radiography modes, the user can utilize the entire range of kV values (40-80kV), while fluoroscopy mode is limited to 40-64kV. In single radiography mode, the user can utilize the entire range of mAs values, while serial radiography and fluoroscopy are limited to 0.04-0.08 mAs.

The MC2 contains various safety features to ensure patient and operator safety. The primary interlocks that ensure system geometry is maintained include a source-to-image distance interlock, an active area interlock, a source-to-skin distance interlock, and a stand-mounted interlock.

Intended Use/Indications for Use

Intended Use:

The MC2 Portable X-ray System is designed to aid clinicians with point-of-care visualization and guidance during X-rays. It is intended for use in clinical environments and is not intended for surgical applications.

Indications for Use:

The MC2 Portable X-ray System is indicated for use by qualified/trained medical professionals on adult and pediatric patients for:

- Handheld orthopedic radiographic procedures of the extremities.
- Handheld orthopedic serial radiographic procedures of the extremities, excluding the shoulder, hip, and knee. Handheld serial radiographic imaging is limited to forward holding position only.

- Stand-mounted orthopedic radiographic, serial radiographic, fluoroscopic, and orthopedic interventional procedures of the extremities, inclusive of shoulders and knees

The device is NOT intended for use during surgery. The device is NOT intended to replace a stationary radiographic or fluoroscopic system, which may be required for optimization of image quality and radiation exposure.

The device is to be used in healthcare facilities where qualified operators are present (e.g., outpatient clinics, urgent cares, imaging centers, sports medicine facilities, occupational medicine clinics).

The device is NOT intended to be used in environments with the following characteristics:

- Aseptic or sterile fields, such as in surgery
- Home or residential settings or other settings where qualified operators are not present
- Vehicular and moving environments
- Environments under direct sunlight
- Oxygen-rich environments, such as near an operating oxygenation concentrator

Contraindications

The MC2 System is contraindicated as follows:

- The MC2 System is NOT intended for bariatric patients.
- The MC2 System is NOT intended for mammography.
- The MC2 System is NOT intended for dental applications.
- The MC2 System is NOT intended to come in contact with non-intact skin.
- The MC2 System is NOT intended for cardiac applications.
- The MC2 System is not intended for use in proximity to pacemakers or implantable cardioverter-defibrillators (ICDs).

Indications for Use Comparison

This submission modifies an existing device previously cleared under K241567.

The subject of the modifications are to the Indications for Use statement of the MC2, specifically:

- Indications for pediatric use.
- Indications for expanded anatomies, inclusive of shoulders and knees.
- Indications for handheld use of the device for DDR captures limited to distal extremities excluding shoulder, hip and knee.

The MC2 Portable X-ray System and the predicate device are both intended for use by qualified/trained medical professionals on adult patients for diagnostic radiographic and interventional fluoroscopic procedures. The MC2 Portable X-ray System has identical procedural and environmental scope as the predicate device. The subject device MC2 is

additionally indicated for use in pediatrics, imaging of the shoulders and knees in stand-mounted configuration, and use of DDR handheld for distal extremities, which are supported by performance testing supplied in this submission. Reference devices M01 (K212654) and Virtual C DRF (K211191) are inclusive of the additional indications sought; specifically, M01 includes Indications for pediatric use and handheld DDR, while DRF includes the desired expanded anatomies.

Technological Comparison

The MC2 Portable X-ray System shares identical technological characteristics with the predicate device.

The following table provides a comparison of the technological characteristics of the MC2 with the predicate and reference devices:

Characteristic	**Subject Device: OXOS MC2**	**Predicate Device: OXOS MC2 (K241567)**	**Reference Device: Micro C M01 (K212654)**	**Reference Device: Virtual C DRF (K211191)**	**Comparison**
Product Code	OXO, OWB, IZL	OXO, OWB, IZL	IZL	OXO, OWB, JAA	Identical to Predicate
Regulation Number	21 CFR 892.1650	21 CFR 892.1650	21 CFR 892.1720	21 CFR 892.1650	Identical to Predicate
Classification Name	Image-intensified Fluoroscopic X-ray System	Image-intensified Fluoroscopic X-ray System	Mobile x-ray system	Image-intensified Fluoroscopic X-ray System	Identical to Predicate
Classification	Class 2	Class 2	Class 2	Class 2	Identical
Intended Use	The MC2 Portable X-ray System is indicated for use by qualified/trained	The MC2 Portable X-ray System is indicated for use by qualified/trained	The Micro C Medical Imaging System, M01 is a handheld and	Intended for use by a qualified/trained medical professionals, who	Similar to predicate. The differences are supported by the reference devices

Characteristic	Subject Device: OXOS MC2	Predicate Device: OXOS MC2 (K241567)	Reference Device: Micro C M01 (K212654)	Reference Device: Virtual C DRF (K211191)	Comparison
	medical professionals on adult and pediatric patients for: Handheld orthopedic radiographic procedures of the extremities. Handheld orthopedic serial radiographic procedures of the extremities, excluding the shoulder, hip, and knee. Handheld serial radiographic imaging is limited to forward holding position only. Stand-mounted orthopedic radiographic, serial radiographic,	medical professionals on adult patients for orthopedic radiographic, orthopedic serial radiographic, orthopedic fluoroscopic, and orthopedic interventional procedures of extremities distal to the shoulders and distal to the knees. The device is not intended for use during surgery. The device is not intended to replace a stationary radiographic system. The device is to be used in healthcare facilities where qualified operators are	portable general purpose X-ray system that is indicated for use by qualified/trained clinicians on adult and pediatric patients for taking diagnostic static and serial radiographic exposures of extremities. The device is not intended to replace a radiographic system that has both variable tube current and voltages (kVp) in the range that may be required for full optimization of image quality and radiation exposure for different exam types.	have full understanding of the safety information and emergency procedures as well of capabilities and function of the device. The device provides radiographic, multiradiographic and fluoroscopic imaging and is used for guidance and visualization during diagnostic radiographic, surgery, and interventional procedures. The device is to be used in healthcare facilities both inside and outside of hospital, in a variety of procedures of the	and performance testing

Characteristic	Subject Device: OXOS MC2	Predicate Device: OXOS MC2 (K241567)	Reference Device: Micro C M01 (K212654)	Reference Device: Virtual C DRF (K211191)	Comparison
	fluoroscopic, and orthopedic interventional procedures of the extremities, inclusive of shoulders and knees The device is not intended for use during surgery. The device is not intended to replace a stationary radiographic or fluoroscopic system, which may be required for optimization of image quality and radiation exposure.	present (e.g., outpatient clinics, urgent cares, imaging centers, sports medicine facilities, occupational medicine clinics).		skull, spinal column, chest, abdomen, extremities, and at the discretion of the medical professional the device may be used for other imaging applications on all patients except neonates (birth to one month) within the limits of the device. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. The system is not intended for mammography applications	
Environment	The device is not intended to be used	The device is not intended to be used	Not specified	Not specified	Identical to predicate

Characteristic	Subject Device: OXOS MC2	Predicate Device: OXOS MC2 (K241567)	Reference Device: Micro C M01 (K212654)	Reference Device: Virtual C DRF (K211191)	Comparison
	in environments with the following characteristics: ● Aseptic or sterile fields, such as in surgery ● Home or residential settings or other settings where qualified operators are not present ● Vehicular and moving environments ● Environments under direct sunlight ● Oxygen-rich environment	in environments with the following characteristics: ● Aseptic or sterile fields, such as in surgery ● Home or residential settings or other settings where qualified operators are not present ● Vehicular and moving environments ● Environments under direct sunlight ● Oxygen-rich environment			

Characteristic	Subject Device: OXOS MC2	Predicate Device: OXOS MC2 (K241567)	Reference Device: Micro C M01 (K212654)	Reference Device: Virtual C DRF (K211191)	Comparison
	s, such as near an operating oxygenation concentrator	s, such as near an operating oxygenation concentrator			
Contraindications	Not for bariatric, mammography, dental, cardiac, non-intact skin, pacemakers	Not for bariatric, mammography, dental, cardiac, non-intact skin, pacemakers	Not for mammography, surgical use	Not for mammography	Identical to predicate
Prescription Use	Rx Only	Rx Only	Rx Only	Rx Only	Identical.
Population	Adults and Pediatric	Adults only	Adults and Pediatric	Adults and Pediatric	The difference in population is supported by the reference devices and performance testing.
Image Type Produced	Fluoroscopy, Static, Serial Radiography, Photography	Fluoroscopy, Static, Serial Radiography, Photography	Static and Serial Radiography	Fluoroscopy, Static, Dynamic Radiography	Identical to Predicate
Device Design	Handheld (Static, Serial, Photography) and	Handheld (Static, Photography) and	Handheld (Static, Serial, Photography)	Mobile Fluoroscopic	Identical to combination of predicate and

Characteristic	Subject Device: OXOS MC2	Predicate Device: OXOS MC2 (K241567)	Reference Device: Micro C M01 (K212654)	Reference Device: Virtual C DRF (K211191)	Comparison
	Portable (Fluoroscopy)	Portable (Serial, Fluoroscopy)			reference devices. This regulatory strategy was discussed and agreed upon with FDA in Q250545, Question 5.
Display	Tablet/Monitor via OXOS App	Tablet/Monitor via OXOS App	Not specified	Workstation monitor	Identical to predicate.
Detector	iRay Mercu0909X, 9×9 in, 5 fps	iRay Mercu0909X, 9×9 in, 5 fps	Teledyne Xineos 1515	Vivix-D1212G, 12×12 in, 20 fps	Identical to Predicate.
MTF	60% @1Lp/mm, 28% @2Lp/mm	60% @1Lp/mm, 28% @2Lp/mm	60% @1Lp/mm	30% @2Lp/mm	Identical to predicate.
DQE	47% @1Lp/mm	47% @1Lp/mm	70% at 0Lp/mm	56% @1Lp/mm	Identical to predicate
Pixel Pitch	139 µm	139 µm	99 µm	145 µm	Identical to predicate
Scintillator	CsI	CsI	CsI	CsI	Identical across devices.
Collimator	Removable pucks + auto/manual collimator	Removable pucks + auto/manual collimator	Removable pucks	Machine-vision collimator	Identical to predicate

Characteristic	Subject Device: OXOS MC2	Predicate Device: OXOS MC2 (K241567)	Reference Device: Micro C M01 (K212654)	Reference Device: Virtual C DRF (K211191)	Comparison
Source to Skin Distance (SSD)	LIDAR	LIDAR	20 cm SSD cone	LIDAR	Identical across devices.
Source to Image Distance (SID)	25–80 cm	25–80 cm	20–45 cm	Unknown	Identical to predicate
Field Visualization	Emitter viewfinder	Emitter viewfinder	Primary Display	Real-time overlay	Identical to predicate
Laser	Class 1 laser	Class 1 laser	Class 1 laser	Class 1 laser	Identical across devices
Focal Spot	0.8 mm	0.8 mm	100 µm	0.6 mm	Identical to predicate
Exposure Time	40–200 ms	40–200 ms	33–99 ms	10 ms	Identical to predicate
mA	1.0–2.0 mA	1.0–2.0 mA	1.0 mA fixed	0.1–2.0 mA	Identical to predicate
kVp	40–80 kVp	40–80 kVp	40–60 kVp	30–80 kVp	Identical to predicate
Software	Embedded software + OXOS App	Embedded software + OXOS App	Custom embedded software	System software	Identical to predicate
Ingress Protection Rating	IP00, IPX8, IP67	IP00, IPX8, IP67	IP00	Unknown	Identical to predicate

Characteristic	**Subject Device: OXOS MC2**	**Predicate Device: OXOS MC2 (K241567)**	**Reference Device: Micro C M01 (K212654)**	**Reference Device: Virtual C DRF (K211191)**	**Comparison**
Image Processing	Zoom, brightness, contrast, etc.	Zoom, brightness, contrast, etc.	Image adjustment tools	Includes image analysis tools	Identical to predicate
Connectivity Options	WiFi, USB-C	WiFi, USB-C	WiFi, USB-C	Ethernet/WiFi	Identical across devices
DICOM	DICOM 3.0	DICOM 3.0	DICOM 3.0	DICOM 3.0	Identical.
Electrical Safety Standards	IEC60601-1:2005 + A2 (2020), IEC60601-1-2:2020, etc.	IEC60601-1:2005 + A2 (2020), IEC60601-1-2:2020, etc.	IEC60601-1:2005, IEC60601-1-2:2014, etc.	Older versions of IEC standards	Meets or exceeds all comparator standards.

Cybersecurity

Following the FDA guidance titled *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (2023)*, the MC2 was risk assessed for security threats separately from device risk assessment using the methodology prescribed in the guidance.

Threat modeling was performed in accordance with the STRIDE methodology. Security controls were implemented in the following categories:

- Authentication controls
- Authorization controls
- Cryptography controls
- Code, data, and execution integrity controls
- Confidentiality controls
- Event detection and logging controls
- Resiliency and recovery controls
- Firmware and software update controls

Security controls were verified and demonstrated adequacy within the MC2's usage environments. Additionally, fuzz testing of vulnerable interfaces and robust third-party penetration testing of the entire system were performed, demonstrating the MC2's security.

Performance Testing

OXOS Medical has completed performance testing to demonstrate the safe and effective use of the MC2 for the expanded Indications for Use statement.

Additionally, comprehensive, task-based image quality studies were conducted to assess the clinical adequacy of the device's imaging performance for pediatric populations and additional indicated anatomies. This study collected radiographic images, radiographic series, and fluoroscopic series for all relevant anatomical indications stated in the Indications for Use. Images were acquired for static radiography, serial radiography, and fluoroscopic modes. Radiologic technologists acquired images in all acquisition modes with appropriately selected techniques, and three reviewers clinically evaluated the image quality, determining them to be clinically adequate for pediatrics and the additional anatomies.

Non-Clinical and Clinical Tests Summary

After feedback received during the review process of the currently marketed MC2 device (K241567), the MC2 system was validated with a Usability Validation study focusing on hand-held DDR that utilized 15 new participants from expected user groups, focusing on a female

population to ensure worst-case ergonomic usability in a simulated use environment to conduct realistic imaging study tasks in handheld radiographic use cases.

The subject MC2 Portable X-ray System therefore was found to be safe and effective for use. This testing supports substantial equivalence of the subject MC2 compared to the predicate device.

Conclusion

The subject MC2 Portable X-ray System is substantially equivalent to the legally marketed predicate device.