December 6, 2024

Oxos Medical, Inc.
% Dhruv Vishwakarma
Director of Regulatory Affairs
Powers Regulatory Consulting
1100 Peachtree St NE
Suite 700
ATLANTA, GA 30309

Re: K241567
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, IZL, OXO
Dated: November 5, 2024
Received: November 7, 2024

Dear Dhruv Vishwakarma:

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

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241567

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 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 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

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Contact Details

	Applicant Information	Correspondent Information
Name	OXOS Medical, Inc.	OXOS Medical, Inc.
Address	1100 Peachtree St NE Suite 700 Atlanta, GA 30309	1100 Peachtree St NE Suite 700 Atlanta, GA 30309
Contact	Mr. Dhruv Vishwakarma	Mr. Dhruv Vishwakarma
Phone	770-375-7840	770-375-7840
Email	dhruv.vishwakarma@oxos.com	dhruv.vishwakarma@oxos.com

Device Information

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

Legally Marketed Predicate Devices

Type	K-Number	Trade Name	Product Code
Predicate	K211191	Virtual C DRF Digital Imaging System	OWB
Reference	K182207	MinXray, Inc. TR90BH	IZL
Reference	K193225	KDR U-ARM	KPR
Reference	K221714	Flat Panel Detector	MQB
Reference	K150150	Rayence 1717SCN	MQB

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 extremities distal to the shoulders and distal to the knees. 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. Single radiography acquisitions may be performed handheld, while serial radiography and fluoroscopy require the emitter to be in a stand-mounted configuration.

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.

The source-to-image distance interlock uses the Tracking System to disallow X-ray acquisition when the device is outside the bounds of source-to-image distance (SID). This acts concurrently with the source-to-skin distance (SSD) interlock which uses the LIDAR system to disallow X-ray acquisition below 30cm source-to-skin distance. Both conditions must be met for X-ray acquisition to be allowed. The active area interlock uses the Tracking System to prevent the X-ray field from extending beyond the bounds of the active area. The stand-mounted interlock prevents handheld X-ray acquisition in serial radiography and fluoroscopy modes.

In addition to the components listed above, the MC2 includes accessories, such as a clinical cart and a wireless foot pedal. The foot pedal should be used for stand-mounted imaging when initiating single, serial or fluoroscopic acquisitions remotely. The clinical cart supports the MC2 for stand-mounted operation and allows the user to position anatomy easily. An accessory stand such as the clinical cart is required to facilitate stand-mounted imaging modes. Radiography and Photo modes may be used without a stand.

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 of distal extremities. 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 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 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

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 a narrower anatomical, procedural, and environmental scope than the Virtual C DRF Digital Imaging System. The MC2 Portable X-ray System is indicated for use by qualified/trained 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.

Technological Comparison

The MC2 Portable X-ray System shares most technological characteristics with the primary predicate device, the Virtual C DRF Digital Imaging System, including principles of operation and design features; however, there are some differences in detailed technological characteristics. Both devices offer single radiographic and fluoroscopic imaging. The MC2 device has longer exposure time capabilities. The MC2 features a higher resolution (pixel pitch) detector and a slightly larger focal spot. MTF and DQE values differ slightly between the two devices. The subject device and the primary predicate both utilize LIDAR to provide the means to maintain a safe source-to-skin distance.

The MinXray, Inc. TR90BH is used as a reference device due to its handheld nature. It is used for performing static radiographic imaging for similar anatomical indications.

The Konica Minolta KDR U-Arm features serial radiographic (DDR) capabilities similar to those of the subject MC2 device. The DDR functionality in the MC2 includes various mitigations to disallow use for guidance. These include a 2 second delay from image acquisition to display of each preview frame, a low-resolution preview display, a lower frame rate during image preview, and a salient disclaimer informing the user that the mode is not to be used for fluoroscopy.

The iRay Venu1717X is an FDA-cleared detector that is very similar in design and technological features to the detector found in the subject MC2 device. The X-ray detection technology is identical in both detectors, with similar DQE and MTF. The reference device has a large 17 x 17” active area.

The Rayence 1717SCN reference device is an FDA-cleared X-ray detector similar to the iRay Mercu0909X found in the subject device.

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

	Subject Device: OXOS MC2 (K241567)	Predicate Device: Virtual C DRF (K211191)	Relevant Reference Device	Comparison
Display	The MC2 system interfaces via the OXOS Device App with a tablet or monitor. An off-the-shelf tablet is optionally supplied with the MC2 or can be supplied by the user.	Display on workstation monitor.	-	The subject device's display is similar to that of other devices, including the reference devices, in that it can be displayed on monitors or tablets.
Detector	iRay Mercu0909X Active Area: 9 x 9 inches Frame rate: 5 fps @ 1×1	Vivix-D1212G Active Area: 12" x 12" Frame rate: 20 FPS @ 1x1	Konica Minolta KDR U-Arm: 348.8 x 425.6 mm (13.7 x 16.8 in) 15 FPS Rayence 1717SCN: 43.18cm x 43.18 cm (17 in x 17 in)	The subject and predicate devices have detectors with equivalent technological characteristics.
MTF	MTF @ 1 Lp/mm, RQA5: 55% MTF @ 2 Lp/mm, RQA5: 23%	MTF @ 2.0 Lp/mm: 30%	Rayence 1717SCN: MTF @ 1 Lp/mm: 59% MTF @ 2 Lp/mm: 26%	The subject device has a similar MTF compared to the predicate device.
DQE	DQE @ 0 Lp/mm: 72% DQE @ 1 Lp/mm: 51% DQE @ 2 Lp/mm: 31% RQA5	DQE @ 1 Lp/mm: 56%	Konica Minolta KDR U-Arm: DQE @ 0 Lp/mm: 72% RQA5 Rayence 1717SCN: DQE @ 0 Lp/mm: 61% DQE @ 1 Lp/mm: 53% DQE @ 2 Lp/mm: 28% RQA5	The subject device has a similar DQE compared to the predicate device.
Pixel Pitch	139µm	145µm	Rayence 1717SCN: 127µm	Similar.
Scintillator	Cesium Iodide (CsI)	Cesium Iodide (CsI)	Cesium Iodide (CsI)	Identical.
Collimator	Removable fixed collimators (pucks) and an automatic collimator with manual stepped adjustment capability for fine adjustments.	Machine-Vision Collimator (Accession 2010848-000)	-	The subject device has a collimation design similar to the predicate device. Both devices use device tracking information to confine the X-ray field to the active area.
Source to Skin Distance (SSD)	LIDAR	LIDAR	-	Identical.
Field Visualization	Viewfinder on emitter screen UI.	A visual display provides real time video images of the patient, and a shaded area within	-	The subject device has a Viewfinder on the emitter to aid patient positioning. The predicate device uses a similar technique to display the x-ray

	Subject Device: OXOS MC2 (K241567)	Predicate Device: Virtual C DRF (K211191)	Relevant Reference Device	Comparison
		the video images represents the location and size of the radiation beam with respect to the patient.		field with respect to the patient in real-time.
Laser	Class 1 laser device compliant with IEC 60825-1:2014 -3rd edition used for Light Detection and Ranging (LIDAR) to indicate the distance from the x-ray source to the target to be diagnosed. Class 1 laser devices compliant with IEC 60825-1:2014 - 3rd edition display a red crosshair used to align patient anatomy.	Unknown.	MinXray TR90BH: Two lasers: Class II; laser diode; max output ≤1.0 mW, wavelength 635 nm	The subject and reference device both similarly utilize lasers for patient positioning.
Focal Spot (IEC)	0.8	SB-80-2K-LD: 0.6	MinXray TR90BH: 0.8	The subject device's focal spot is similar to the predicate and reference devices.
Exposure Time / Pulse Duration	40–200 ms	10 ms	MinXray TR90BH: 0.01–0.3 sec (10–300 ms). 0.01 sec (10 ms) Step	The subject device exposure times are similar to the predicate and reference device's exposure time.
mA	1.0–2.0 mA	0.1–2.0 mA	MinXray TR90BH: 15 mA @ 82–90 kVDC. (2 kVP steps)	The subject device's mA is identical to the predicate device.
kVp	40–80 kVp	30–80 kVp	MinXray TR90BH: 40–90kVp	The kVps of all devices are similar.
Software	Custom software is embedded within the emitter, cassette, and foot pedal to operate the device. The OXOS Device App (non-embedded) is for image viewing, study management, collimation control, image processing for DICOM 3.14 greyscale calibration, and display of messages and alerts.	Virtual C DRF software	N/A	All predicate and reference devices have software that supports the device.
Ingress Protection Rating	IP00 (E1 Emitter, C1 Cassette, H1 Wired Charger) IPX8 (F1 Foot Pedal) IP67 (P1 Case)	Unknown	N/A	N/A.
Image Processing	User Interface can drag, zoom, rotate, adjust brightness, contrast, and sharpness.	Includes software for image capture and analysis.	All include software for image capture and analysis.	Similar.
Connectivity Options	WiFi, USB-C ports	Ethernet or Wi-Fi	MinXray TR90BH: RJ45 port for DR interface	The predicate and reference devices all have various connectivity options.
DICOM	DICOM 3.0 compliant	DICOM	All are DICOM 3.0 compliant	Identical.
Electrical Safety	IEC60601-1:2005 + A2 (2020) IEC60601-1-2:2020	IEC60601-1:2005 + A1 (2012) IEC60601-1-2:2007	-	Identical.

	Subject Device: OXOS MC2 (K241567)	Predicate Device: Virtual C DRF (K211191)	Relevant Reference Device	Comparison
	IEC60601-1-3:2008 + A2 (2021) IEC60601-2-28:2017 IEC60601-2-43:2022 IEC60601-2-54:2022 NEMA PS 3.1-3.20	IEC60601-1-3:2008 IEC60601-2-28:2010 IEC60601-2-43:2010 IEC60601-2-54:2009 NEMA PS 3.1-3.20		

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

All components of the MC2, including software, were verified and validated to demonstrate compliance with the appropriate regulations and in accordance with the risk profile analysis. A third-party testing laboratory performed performance testing of the MC2 in accordance with the applicable standards. The third-party testing laboratory and formal internal testing also tested all safety interlocks. All forms of testing showed the MC2 to be compliant with the relevant standards and safe and effective in the procedures and scenarios outlined in the Indications for Use.

A comprehensive, task-based image quality study was conducted to assess the clinical adequacy of the device's imaging performance. 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 five radiologists clinically evaluated the image quality.

Non-Clinical and Clinical Tests Summary and Conclusions

OXOS performed nonclinical bench testing on the MC2 Portable X-ray System to demonstrate the system performance met required design inputs and user needs and is safe for its intended use. The testing included the verification and validation of: the design and software per OXOS specifications, the adequacy of image quality for the MC2 intended use, the conformance to voluntary standards evaluating device safety and performance, and the usability of the device, demonstrating that MC2 is safe and effective for its intended users.

The MC2 Portable X-ray System met bench testing acceptance criteria as defined in the test protocols. This testing supports substantial equivalence of the MC2 technological characteristics and performance compared to the predicate device.

Standards

The MC2 complies with the following standards, as applicable:

Regulation or Standard	**K241567 - 510(k) Summary**
21 CFR 801	Labeling
21 CFR 1020.30(a), (b), (d), (e), (g), (j), and (q) Sections (c), (h), (k), (l), (m), (n), and (o) met via conformity to IEC 60601-1-3 and 60601-2-54	Diagnostic X-ray systems and their major components
21 CFR 1020.31 met via conformity to IEC 60601-1-3 and IEC 60601-2-54	Radiographic equipment
21 CFR 1020.32(d)(3)(v), and (g) Sections (a), (b), (c), (d)(1), (d)(2), (d)(3)(i) – (iv), (d)(4), (f), (h), (i), (j), and (k) met via conformity to IEC 60601-1-3, IEC 60601-2-54, and IEC 60601-2-43	Fluoroscopic equipment

47 CFR 18	Telecommunication
ISO 14971 Third Edition 2019-12	Medical devices - Application of risk management to medical devices
IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-2-28 Edition 3.0 2017-06	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
IEC 60601-2-43 Edition 2.2 2019-10 CONSOLIDATED VERSION	Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures
IEC 60601-2-54 Edition 2.0 2022-09	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes
ISO 10993-1 Fifth edition 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
NEMA PS 3.1 - 3.20 2022d Digital Imaging and Communications in Medicine (DICOM) Set	Digital Imaging and Communications in Medicine (DICOM) Set
IEC 62563-1 Edition 1.2 2021-07 CONSOLIDATED VERSION	Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods

IEC 61910-1 Edition 1.0 2014-09	Medical electrical equipment - Radiation dose documentation - Part 1: Radiation dose structured reports for radiography and radioscopy
IEEE ANSI USEMCSC C63.27-2021	American National Standard for Evaluation of Wireless Coexistence
AAMI TIR69:2017/(R2020)	Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems.
IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	Medical devices - Part 1: Application of usability engineering to medical devices
IEC 62133-2 Edition 1.0 2017-02	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
Section 38.3 of the UN Manual of Tests and Criteria	Lithium metal and lithium ion batteries

The MC2 complies with 21 CFR Subchapter J, including 21 CFR 1020.30 to 1020.32, partially by conforming with IEC 60601-1-3 Edition 2.2 (2021), IEC 60601-2-54 Edition 2.0 (2022), and IEC 60601-2-43 Edition 2.2 (2019), in accordance with section 14(c)(1)(A) of the FD&C Act as outlined in “Medical X-Ray Imaging Devices: Conformance with IEC Standards,” dated February 21, 2023.