February 4, 2022

OXOS Medical, Inc.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

Re: K212654
Trade/Device Name: Micro C Medical Imaging System, M01
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL
Dated: January 27, 2022
Received: January 28, 2022

Dear Prithul Bom:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*

K212654

Device Name
Micro C Medical Imaging System, M01

Indications for Use *(Describe)*

The Micro C Medical Imaging System, M01 is a handheld and 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.

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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Section 5
510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Micro C Medical Imaging System, M01 Traditional 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Submitter: OXOS Medical, Inc
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Submission Contact: Mo Khosravanipour
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Grace Powers, MS, MBA, RAC
Founder/Principal Consultant
Powers Regulatory Consulting
Email: grace@powersregulatory.com

Submission Date: July 21, 2021

Subject Device: Trade Name: Micro C Medical Imaging System, M01
Common Name: System, X-Ray, Mobile
Regulation: 21 CFR § 892.1720
Regulatory Classification: 2
Product Code: IZL
Classification Panel: Radiology

Predicate Device: Legally marketed device to which substantial equivalence is claimed:
Micro C Medical Imaging System, M01 (K211473)

Device Description:
The Micro C Medical Imaging System, M01 (subject device) is a handheld X-ray system designed to aid clinicians with point of care visualization through diagnostic X-rays of distal extremities. The device allows a clinician to select desired technique factors best suited for their patient anatomy. The Micro C Medical Imaging System, M01 consists of three major subsystems: The Emitter, Cassette, and Control Unit. The System is intended to interface an external Monitor (touchscreen or non-touchscreen display), keyboard and a mouse, and can provide a remote operator interface over the network to a laptop. The

Micro C Medical Imaging System, M01 utilizes a computer vision positioning system to allow the emitter to be positioned above the patient anatomy and aligned to the cassette by the operator. The device is used in a clinical environment. A description of the three major sub-systems is listed below.

- Emitter: This component contains the operator control panel, X-ray tube, and computer vision camera. The control panel allows the operator to control the major functions of the device, including the technique factors. This component is controlled and held in the operator's hand.

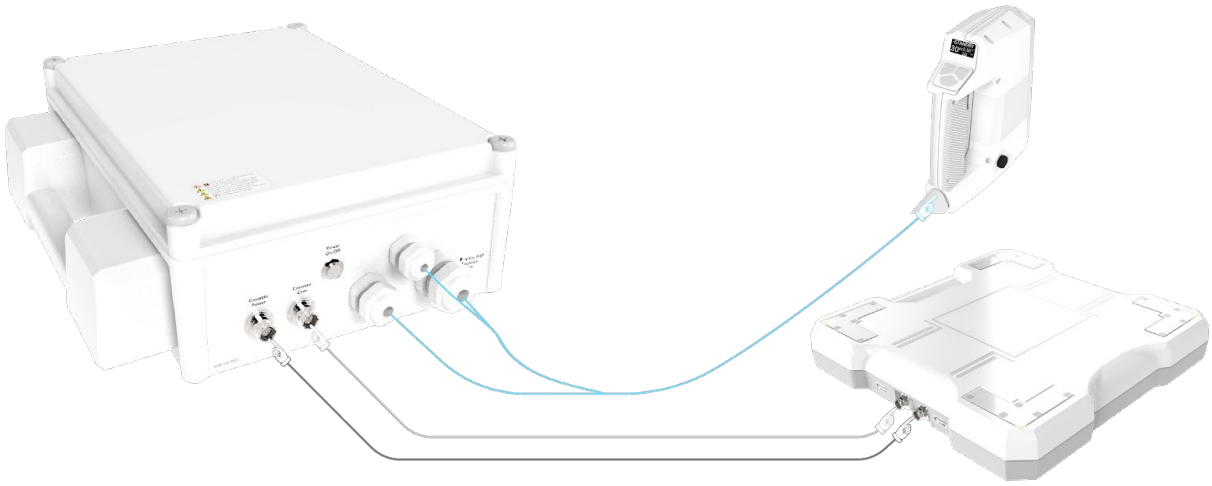
- Cassette: This component contains the X-ray detector that collects the X-ray energy and provides a digital representation to the control unit for eventual display. This component also contains status lights and IR lights to assist in X-ray field positioning. The patient anatomy of interest is placed on top of this module.

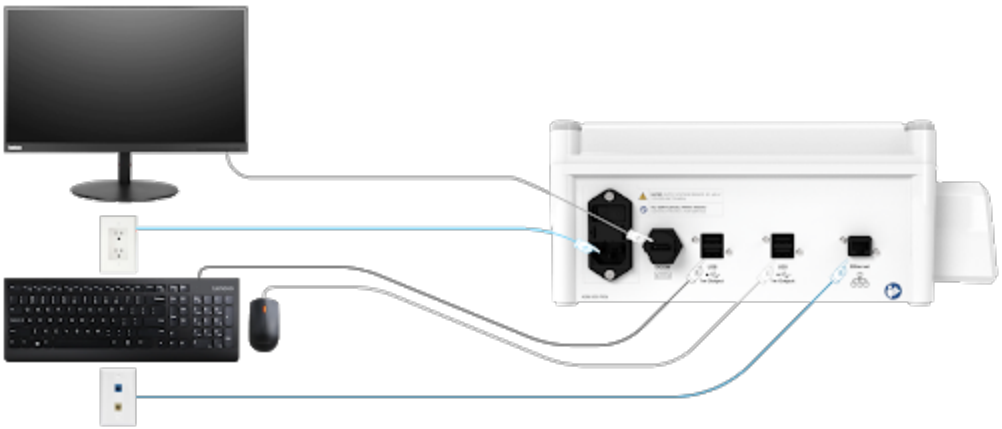
- Control Unit: This component contains the High Voltage generator, computing power, monitor and keyboard inputs, and other electronics required for the functioning of the device. This module is typically placed on a shelf, cart, counter, or other flat surface convenient to the operator and environment.

The system is intended to work in conjunction with a DICOM monitor, keyboard and a mouse and the mains power outlet.

The Micro C Medical Imaging System, M01 has custom validated software that includes a user interface that allows the operator to view and adjust captured radiographs and transfer radiographs to a PACS server or flash drive.

Figure 5-1: Subject Device – Micro C Medical Imaging System, M01





Intended Use:
The M01 System is a hand-held X-ray system designed to aid clinicians with point of care visualization through diagnostic X-rays of extremities.

Indications for Use:
The Micro C Medical Imaging System, M01 is a handheld and 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.

Technological Characteristics
The Micro C Medical Imaging System, M01 is identical to the predicate device cleared via K211473. The purpose of this submission is to update the software to include AiLARA modes as described below. The table below compares the subject and predicate device.

Table 5-2: Device Comparison

	Subject Device: Micro C Medical Imaging System, M01	**Predicate Device: Micro C Medical Imaging System, M01 (K211473)**	**Comparison**
Product Code	IZL (Mobile X-Ray System)	IZL (Mobile X-Ray System)	Identical
Regulation	21 CFR 892.1720	21 CFR 892.1720	Identical
Classification Name	Mobile X-Ray System	Mobile X-Ray System	Identical
Classification	Class 2	Class 2	Identical
Indication for Use	The Micro C Medical Imaging System, M01 is a handheld and portable general purpose X-ray system that is indicated for use by	The Micro C Medical Imaging System, M01 is a handheld and portable general purpose X-ray system that is indicated for use	Identical

	Subject Device: Micro C Medical Imaging System, M01	Predicate Device: Micro C Medical Imaging System, M01 (K211473)	Comparison
	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.	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.	
Contraindications	● Surgical applications ● Pediatric patients ● Fluoroscopy ● For cardiac and vascular applications ● Mammography ● Dental applications ● Contact with non-intact skin	● Surgical applications ● Pediatric patients ● Fluoroscopy ● For cardiac and vascular applications ● Mammography ● Dental applications ● Contact with non-intact skin	Identical
Age of Device Use	Adults and Pediatric	Adults and Pediatric	Identical
Principle of Operation	General purpose diagnostic X-ray	General purpose diagnostic X-ray	Identical
Image type produced	Static, serial radiographic and photographic images for convenience.	Static, serial radiographic and photographic images for convenience.	Identical
Detector	6 x 6” digital detector	6 x 6” digital detector	Identical
Collimator	The removable fixed collimators (referred to as pucks)	The removable fixed collimators (referred to as pucks)	Identical
Weight	Emitter: 2.86kg (6.3lbs)	Emitter: 2.86kg (6.3lbs)	Identical

	Subject Device: Micro C Medical Imaging System, M01	**Predicate Device: Micro C Medical Imaging System, M01 (K211473)**	**Comparison**
	Cassette: 6.5kg (14.3lbs) Control Unit: 8.6kg (19.0lbs)	Cassette: 6.5kg (14.3lbs) Control Unit: 8.6kg (19.0lbs)	
Dimension/ Size	Emitter: 9.3”H x 3.5”W x 8.3”L (excluding SSD Cone) Cassette: 15.5”H x 15.5”W x 2.8”L Control Unit: 16.4”H x 12.9”W x 5.5”L	Emitter: 9.3”H x 3.5”W x 8.3”L (excluding SSD Cone) Cassette: 15.5”H x 15.5”W x 2.8”L Control Unit: 16.4”H x 12.9”W x 5.5”L	Identical
Triggering Mechanism	Two stage triggering	Two stage triggering	Identical
Minimum Source to skin distance (SSD)	20 cm SSD Cone ensures minimum SSD of 20 cm	20 cm SSD Cone ensures minimum SSD of 20 cm	Identical
Source to Detector distance	20 - 45 cm	20 - 45 cm	Identical
Light Field	Virtual light field on Monitor UI. No projected light field.	Virtual light field on Monitor UI. No projected light field.	Identical
Energy Source	120 VAC / 60 Hz (no rechargeable battery)	120 VAC / 60 Hz (no rechargeable battery)	Identical
Exposure Time	33 ms - 99 ms	33 ms, 66 ms, 99 ms	Similar- The overall range is identical. Single AiLARA mode allows for ms values throughout the range. Serial AiLARA mode has a fixed output of 33 ms.
mA	1.0 mA fixed	1.0 mA fixed	Identical
kVp	40kVp-60kVp	40kVp, 50kVp, and 60kVp	Similar- The overall range is identical. AiLARA allows for kVp values throughout the range.
Scintillator	Cesium Iodide (CsI)	Cesium Iodide (CsI)	Identical
Resolution/ Pixel size	99 µm	99 µm	Identical
DQE @ 0Lp/mm	70%	70%	Identical
MTF @ 1 Lp/mm, RQA5	60%	60%	Identical

	Subject Device: Micro C Medical Imaging System, M01	Predicate Device: Micro C Medical Imaging System, M01 (K211473)	Comparison
Ingress Protection Rating	IP00	IP00	Identical
Image Processing	User Interface can be used to drag, zoom, rotate and also adjust brightness, contrast, and sharpness.	User Interface can be used to drag, zoom, rotate and also adjust brightness, contrast, and sharpness.	Identical
Connectivity Options	WiFi, Ethernet, Four USB 2.0 ports	WiFi, Ethernet, Four USB 2.0 ports	Identical
DICOM	Yes- DICOM 3.0 Compliant	Yes- DICOM 3.0 Compliant	Identical
Device Package Contents	● Cassette ● Control Unit ● Emitter ● Collimation Pucks ● SSD Cone ● Cassette Power Cable ● Cassette Data Cable ● Control Unit Power Cable ● Connector Covers ● Instructions for Use ● Case	● Cassette ● Control Unit ● Emitter ● Collimation Pucks ● SSD Cone ● Cassette Power Cable ● Cassette Data Cable ● Control Unit Power Cable ● Connector Covers ● Instructions for Use ● Case	Identical

AiLARA Software

The purpose of this Traditional 510(k) is to update the Micro C Medical Imaging System, M01 software to include two additional modes of use referred to as AiLARA. AiLARA is a static artificial intelligence (AI) based algorithm in the updated software. AiLARA adds two additional modes for the M01 device: Single AiLARA and Serial AiLARA. In these modes, the device determines and recommends a power setting and an exposure time for the X-ray without user input. This mode may help ensure that a clinically relevant image is taken and reduce overexposures and retaking of images.

The Micro C software, including the new AiLARA algorithm, has a Moderate level of concern per with *Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (2005)*; software development documentation was provided in accordance with the guidance. There was no change to the Micro C software level of concern with the addition of the AiLARA algorithm. The software development lifecycle followed *IEC 62304:2015, Medical device software – Software life cycle processes.* Risk analysis to address the new algorithm was performed in accordance with *ISO 14971:2019, Medical Devices – Application of Risk Management to Medical Devices.*

Non-Clinical Performance Data

Testing specific to the Micro C software with AiLARA modes was performed and included with the 510(k) submission:

Table 5-3: Non-Clinical Performance Data

Performance Test	Description
AiLARA Algorithm Verification	AiLARA's full development dataset was split into a training set (80% of the data) and a testing set for algorithm verification (20% of the data) per Good Machine Learning Practices as outlined in FDA's *Proposed Regulatory Framework for Modifications to Artificial intelligence/Machine Learning (AI/ML) Based Software as a Medical Device (SaMD)(2019)*. AiLARA's model was trained, and at the end of every epoch, the full testing set was sent into the model and was predicted to show the model's performance on unseen data. The model was able to learn the trend of the training dataset (truth). The mean squared error of the training and verification testing datasets were plotted, and the trend lines showed that the model had learned the general trend present in the data. Both training and testing Mean Squared Error and Mean Absolute Error showed that additional training (epochs) would have no added benefit.
Software Verification	Software verification was performed to ensure the updated Micro C software met system-level software requirements. Software outputs met the expected result in all cases, with no anomalies found.
Image Quality Validation Study	An image quality study validation dataset was collected after the AiLARA algorithm was frozen, finalized, and transferred to the Micro C device. This validation set was completely independent of the algorithm training and verification testing set. The emitter can move freely in space (not attached to the detector), therefore the validation images were collected with independent inputs that the algorithm had not seen previously. The independent inputs were achieved by taking images of phantoms at different emitter orientations and angles (geometries). The validation dataset included images taken from ankle, elbow, hand, foot, knee, toe, and wrist phantoms; each phantom was captured at multiple distinct SIDs that spanned the full device SID range of 20 cm to 45 cm. Additionally, each phantom view/SID combination was captured at multiple orientations. Once the validation images were collected, the images were reviewed and rated by board certified radiologists and an orthopedic surgeon. All images were determined to be diagnostically and clinically relevant.
Radiation Dose Testing	AiLARA technique and dose evaluation testing was performed to evaluate AiLARA mode's radiation outputs as compared to diagnostic reference levels from literature, to ensure an acceptable amount of radiation was delivered. Additionally, AiLARA's dose outputs from the auto-selected techniques were compared to the predicate device's manual mode dose outputs that result from the techniques recommended in the Instructions for Use. Results showed that all AiLARA dose values were below the established Diagnostic Reference

	Levels (DRLs) and there was no statistical difference between AiLARA and Manual mode calculated entrance skin exposure doses.
Radiation Dose Testing on Small/Pediatric Anatomies	Testing was conducted to evaluate AiLARA's radiation outputs for small size extremity anatomies (representing low thicknesses seen for small patients, especially pediatrics) as compared to diagnostic reference levels from literature to ensure an acceptable amount of radiation was delivered. This study also included recording dose outputs at different Source to Image Distance (SID) and emitter orientation configurations to ensure doses are consistently acceptable at various emitter orientations and small anatomy thicknesses. Results showed that all AiLARA dose values were below the established Diagnostic Reference Levels (DRLs) for small size anatomies, and doses were similar among captures for each orientation within the same target thickness and SID category.
Usability Evaluation	A usability evaluation was performed for the addition of the AiLARA modes for single radiography and serial radiography (DDR) imaging to ensure the Micro C Medical Imaging System, M01 has acceptable use-related risks and effectiveness during use. The study included 15 participants who were licensed to perform x-ray procedures and had previous experience operating x-ray devices. All the identified critical use tasks were completed with a passing result by 100% of participants. The usability evaluation was performed in accordance with *IEC 62366-1:2020, Medical devices - Part 1: Application of usability engineering to medical devices* and *Guidance for Industry and FDA Staff – Applying Human Factors and Usability Engineering to Medical Devices (2016).*

In addition, the following specific FDA guidance documents were utilized in the device development to ensure the safety of this device for both the operators and patients:

- Guidance for Medical X-ray Imaging Devices Conformance with IEC Standards (2019)
- Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices (2016)
- Radiation Safety Considerations for X-ray Equipment Designed for Hand-held Use (2008)
- Pediatric Information for X-ray Imaging Device Premarket Notifications (2017)

Clinical Performance Data

Non-clinical data generated using imaging phantoms representative of the intended patient populations was sufficient to support the updates to the Micro C device software; no clinical studies were performed. The determination of substantial equivalence is not based on an assessment of clinical performance data.

Conclusion

The Micro C Medical Imaging System, M01 is identical in physical design to the legally marketed predicate device. The updated software is acceptable as demonstrated by the performance data and does not raise different questions of safety and effectiveness.