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

June 4, 2021

Re: K211473
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: May 11, 2021
Received: May 12, 2021

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,

For

Thalia T. Mills, Ph.D.
Director
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)*
K211473

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5
510(k) Summary
K211473

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:
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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: April 16, 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 (K203658)
Common Name: System, X-Ray, Mobile
Regulation: 21 CFR § 892.1720
Regulatory Classification: 2
Product Code: IZL
Classification Panel: Radiology

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.

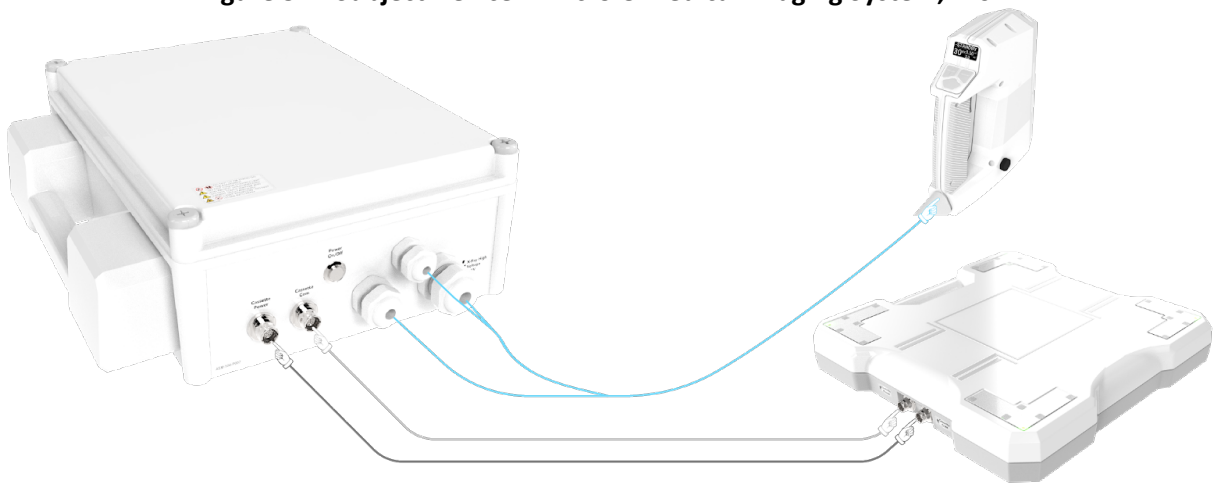
- Cassette: This component contains the X-ray detector that collects the X-ray energy and provides a digital representation to the control unit for eventual display. This component also contains status lights and IR lights to assist in X-ray field positioning. The patient anatomy of interest is placed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

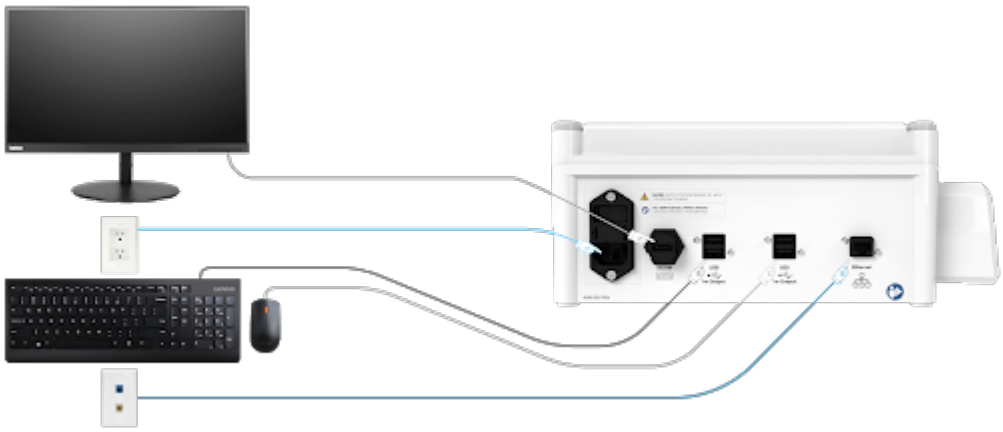
- Control Unit: This component contains the High Voltage generator, computing power, monitor and keyboard inputs, and other electronics required for the functioning of the device. This module is typically placed on a shelf, cart, counter, or other flat surface convenient to the operator and environment.

The system is intended to work in conjunction with a DICOM monitor, keyboard and a mouse and the mains power outlet. These are accessories are not included in the submission.

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. The device software is based on the predicate device and no changes to the software were performed for this submission.

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 K203658. The purpose of this submission is to add the pediatric population to the indication and to allow use in surgery.

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 (K203658)**	**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	The Micro C Medical Imaging System, M01 is a handheld and portable general purpose X-ray system	Different- The subject device can be used in pediatric populations.

	for use by qualified/trained clinicians on adult 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.	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.	
Age of Device Use	Adults and Pediatric	Adults	Different- The subject device can be used in pediatric populations.
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) Cassette: 6.5kg (14.3lbs) Control Unit: 8.6kg (19.0lbs)	Emitter: 2.86kg (6.3lbs) Cassette: 6.5kg (14.3lbs) Control Unit: 8.6kg (19.0lbs)	Identical
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	33ms, 66ms and 99ms	33ms, 66ms and 99ms	Identical
mA	1.0 mA fixed	1.0 mA fixed	Identical
kVp	40kVp, 50kVp, and 60kVp	40kVp, 50kVp, and 60kVp	Identical
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
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	● Cassette ● Control Unit ● Emitter ● Collimation Pucks ● SSD Cone ● Cassette Power Cable ● Cassette Data Cable ● Control Unit Power Cable	Identical

	● Connector Covers ● Instructions for Use ● Case	● Connector Covers ● Instructions for Use ● Case	

Non-Clinical Performance Data

Testing specific to the use in surgery was performed and includes:

- Usability testing for use in surgery
- Cleaning and Disinfection Studies

The following specific guidance document was 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
- Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices
- Radiation Safety Considerations for X-ray Equipment Designed for Hand-held Use
- Pediatric Information for X-ray Imaging Device Premarket Notifications

Conclusion

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