% Prithul Bom
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
SAINT PAUL, MINNESOTA 55114

January 12, 2021

Re: K203658
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: December 14, 2020
Received: December 15, 2020

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)*
Unknown K203658

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 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

K203658

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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Atlanta, GA 30309
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Submission Contact: Mo Khosravanipour
Director of Program Management
OXOS Medical, Inc.
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Grace Powers, MS, MBA, RAC
Founder/Principal Consultant
Powers Regulatory Consulting
Email: grace@powersregulatory.com

Submission Date: November 16, 2019

Subject Device: Trade Name: Micro C Medical Imaging System, M01
Common Name: Mobile X-Ray System
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:
Nomad MD 75kV Handheld X-Ray System (K140723)

Reference Devices: KDR™ AU-DDR System Advanced U-Arm with Dynamic Digital Radiography and KDR™ AU System Advanced U-Arm with Static Digital Radiography (K193225)
Faxitron VisionCT (K173309)

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.

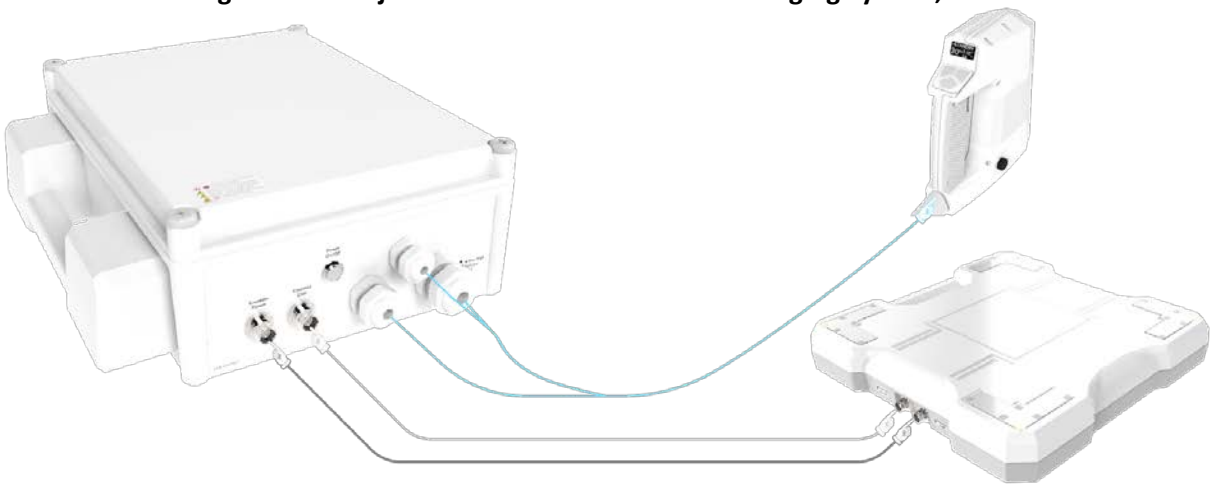
- Cassette: This component contains the X-ray detector that collects the X-ray energy and provides a digital representation to the control unit for eventual display. This component also contains status lights and IR lights to assist in X-ray field positioning. The patient anatomy of interest is placed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

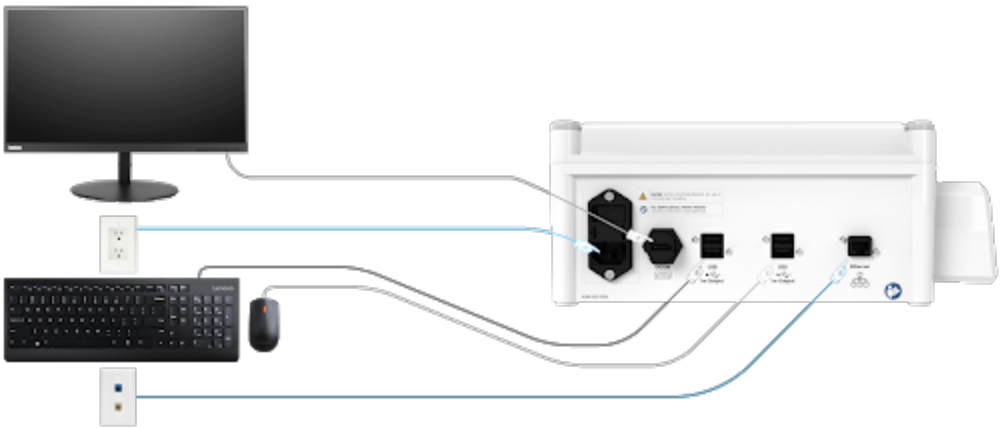
- Control Unit: This component contains the High Voltage generator, computing power, monitor and keyboard inputs, and other electronics required for the functioning of the device. This module is typically placed on a shelf, cart, counter, or other flat surface convenient to the operator and environment.

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 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 has similar technological characteristics as the predicate device, Nomad MD 75kV Handheld X-Ray System cleared via K140723. The Micro C Medical Imaging System, M01 also includes a detector. The detector is identical to the Faxitron VisionCT (K173309).
The Micro C Medical Imaging System, M01 also includes serial radiography similar to the reference device KDR™ AU-DDR System Advanced U-Arm with Dynamic Digital Radiography and KDR™ AU System Advanced U-Arm with Static Digital Radiography cleared via K193225. The table below compares the subject, predicate and reference device. A comparison of the detectors is in the second table below.

Table 5-2: Device Comparison

	Subject Device: Micro C Medical Imaging System, M01	**Predicate Device: Nomad MD 75kV Handheld X-Ray System K140723**	**Reference Device: KDR™ AU-DDR System Advanced U-Arm K193225**
Product Code	IZL (Mobile X-Ray System)	IZL (Mobile X-Ray System)	KPR (System, X-Ray, Stationary), MQB (Solid State X-Ray Imager (Flat Panel/Digital Imager)
Regulation	21 CFR 892.1720	21 CFR 892.1720	21 CFR 892.1680
Classification Name	Mobile X-Ray System	Mobile X-Ray System	Stationary X-ray System
Classification	Class 2	Class 2	Class 2

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 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.	The NOMAD MD is a handheld and portable general purpose X-ray system. The device uses a fixed tube current and voltage (kVp) and, therefore, is limited to taking diagnostic X-rays of extremities. It is intended to be used by a qualified and trained clinician on both adult and pediatric patients. It is not intended to replace a radiographic system with variable tube current and voltage (kVp) which may be required for full optimization of image quality and radiation exposure for different exam types.	The KDR™ AU-DDR System Advanced U-Arm with Dynamic Digital Radiography and KDR™ AU System Advanced U-Arm with Static Digital Radiography is indicated for use by qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic static and serial radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position (not for mammography).
Age of Device Use	Adults	Adults and Children	Adults and Children
Principle of Operation	General purpose diagnostic X-ray	General purpose diagnostic X-ray	General purpose diagnostic X-ray
Image type produced	Static, serial radiographic and photographic images for convenience.	Static images only	Static or serial radiographic images
Detector	6 x 6” digital detector	No detector provided.	16.7 x 16.7” digital detector
Collimator	The removable fixed collimators (referred to as pucks)	Four manually and steplessly adjustable shutters with LED Light Field Center Indicator to limit the X-ray.	Six pairs of motorized automatic collimation with manual override possible, light field Indicator and two Lasers and Camera.
Weight	Emitter: 2.86kg (6.3lbs) Cassette: 6.5kg (14.3lbs) Control Unit: 8.6kg (19.0lbs)	11.0lbs	Stationary device
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	9.5”H x 5.25”W x 10”L (excluding Source Skin guard)	Stationary device with U-Mount arm and X-ray table

	Control Unit: 16.4”H x 12.9”W x 5.5”L		
Triggering Mechanism	Two stage triggering	Two stage triggering	Start button on the user interface after set up.
Minimum Source to skin distance (SSD)	20 cm SSD Cone ensures minimum SSD of 20 cm	30 cm Source Skin Guard ensures minimum SSD of 30 cm	Unknown
Source to Detector distance	20 - 45 cm	Not limited	100 - 200 cm
Light Field	Virtual light field on Monitor UI. No projected light field.	Projected light field	Projected light field
Energy Source	120 VAC / 60 Hz (no rechargeable battery)	Rechargeable 14.4V DC NiCd battery pack (also contains an AC to DC power supply)	480 VAC/ 60Hz (generator)
Exposure Time	33ms, 66ms and 99ms	20 – 990ms in 10ms increments	1-1000 ms in various increments
mA	1.0 mA fixed	2.0 mA fixed	100-1000 mA in various increments
kVp	40kVp, 50kVp, and 60kVp	75 kVp fixed	40-150 kVp in various increments
Ingress Protection Rating	IP00	IP0; do not operate under wet conditions	Unknown
Image Processing	User Interface can be used to drag, zoom, rotate and also adjust brightness, contrast, and sharpness.	Not applicable	User interface has optional post-processing functions such as brightness, sharpness, annotations, stitching and other functions.
Connectivity Options	WiFi, Ethernet, Four USB 2.0 ports	Not applicable	Ethernet, USB ports
DICOM	Yes- DICOM 3.0 Compliant	Not applicable	Yes- DICOM 3.0 Compliant
Device Package Contents	● Cassette ● Control Unit ● Emitter ● Collimation Pucks ● SSD Cone ● Cassette Power Cable ● Cassette Data Cable ● Control Unit Power Cable ● Connector Covers	● Nomad MD device ● Spare Battery ● Charging Cradle ● AC-to-DC Power Supply	● A floor and wall-mounted Positioner (also referred to as a stand) ● Generator ● Off-the-shelf computer with proprietary software (also referred to as an acquisition workstation)

	● Instructions for Use ● Case		

Faxitron VisionCT cleared under K173309 contains the identical detector (Xineos-1515 manufactured by Teledyne DALSA) as the subject device. The Faxitron VisionCT is a stationary X-ray but is used for specimen radiography.

Table 5-3: Detector Comparison

	Subject Device: Micro C Medical Imaging System, M01	**Reference Device: Faxitron VisionCT (K173309).**	**Reference Device: KDR™ AU-DDR System Advanced U-Arm K193225**
Scintillator	Cesium Iodide (CsI)	Cesium Iodide (CsI)	Cesium Iodide (CsI)
Resolution/ Pixel size	99 µm	99 µm	100 µm
DQE @ 0Lp/mm	70%	70%	72%
MTF @ 1 Lp/mm, RQA5	60%	60%	Unknown

Note: The predicate device does not have a detector.

Non-Clinical Performance Data

Testing was performed successfully according to the following standards and CFR:

- ISO 14971 Edition 2 2007 Application of risk management to medical devices (FR Recognition number 5-40)
- 21 CFR 1020.30 Diagnostic X-ray systems and their major components (met via conformity to IEC 60601-1-3 and 60601-2-54, and 21 CFR 1020.30 parts (a), (b), (d), (e),(g), (j), and (q))
- 21 CFR 1020.31 Radiographic equipment (met via conformity to IEC 60601-1-3 and 60601-2-54)
- IEC 60601-1 Edition 3.1 2005 Requirements for Medical Electrical Equipment (FR Recognition number 19-4)
- IEC 60601-1-2 Edition 4 2014 Requirements for Medical Electrical Equipment (FR Recognition number 19-8)
- IEC 60601-1-3 Edition 2.1 2013 Requirements for Medical Electrical Equipment (FR Recognition number 12-269)
- IEC 60601-1-6 Edition 3.1 2013 Requirements for Medical Electrical Equipment, and IEC 62366-1 Edition 1.0 2015 Application of usability engineering to medical devices (FR Recognition number 5-89)
- IEC 60601-2-28 Edition 3.0 2017 Requirements for X-ray Tube Assemblies (FR Recognition number 12-309)
- IEC 60601-2-54 Edition 1.1 2015 Requirements for Medical electrical equipment for radiography (FR Recognition number 12-296)
- IEC 62304 Edition 1.1 2015 for all software product lifecycle development (FR Recognition number 13-79)
- ISO 10993-1 Edition 5 2018 (FR Recognition number 2-258)
- 21 CFR 801: Labeling
- IEC 60825 Edition 3.0 2014 requirements for Lasers (FR Recognition number 12-273)
- DICOM Standard when interfacing with PACS

Additional Non-Clinical performance testing conducted includes:

- Various Functional Testing
- Image Quality Study
- Usability Testing
- Cleaning Study

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

Conclusion

The Micro C Medical Imaging System, M01 is similar to the legally marketed predicate device as demonstrated by the same intended use, similar technologies and performance data, and does not raise different questions of safety and effectiveness.