Micro-X Ltd.
℅ Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

July 17, 2020

Re: K201488
Trade/Device Name: Rover
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL, MQB
Dated: June 1, 2020
Received: June 4, 2020

Dear Mr. Kamm:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201488

Device Name
Rover

Indications for Use *(Describe)*
The device is designed to perform radiographic x-ray examinations on pediatric and adult patients, in all patient treatment areas.

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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510(k) Summary: 510(k) Number K201488

MICRO-X

Limited
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Phone: +61 8 7099 3966
Email: admin@micro-x.com

Date: July 14, 2020

Prepared by: Derek Rogers, Quality and Regulatory Manager

1) **Identification of the Device:**
   Trade/Device Name: Rover
   Regulation Number: 21 CFR 892.1720
   Regulation Name: Mobile x-ray system
   Regulatory Class: II
   Product Codes: IZL, MQB.
   Common/Usual Name: Digital Mobile Diagnostic X-Ray System

2) **Equivalent legally marketed device: K173924,**
   Trade/Device Name: DRX-Revolution Nano Mobile X-ray System
   Regulation Number: 21 CFR 892.1720
   Regulation Name: Mobile x-ray system
   Regulatory Class: II
   Product Codes: IZL, MQB.
   Common/Usual Name: Digital Mobile Diagnostic X-Ray System

3) **Reference devices: We employ these cleared devices without modification:**
   i) Fujifilm FDR D-EVO Series: K142003; K192932
      Regulation Number: 21 CFR 892. 1680
      Regulation Name: Stationary x-ray system
      Regulatory Class: II
      Product Code: MQB
   ii) The Fuji FDX Console Advance DR-ID 300CL Software cleared in K192932
      Regulation Number: 21 CFR 892.2050
      Regulation Name: Picture archiving and communications system
      Regulatory Class: II
      Product Code: LLZ

4) **Indications for Use:** The device is designed to perform radiographic x-ray examinations on pediatric and adult patients, in all patient treatment areas.

5) **Description of the Device**: The Rover product concept was developed under a contract from the Australian Department of Defense to fulfil a need for a full performance digital medical x-ray imager, light enough to be used in deployed medical facilities.
   Key Design Features:

- Full trauma imaging capability 40-110kV, 0.2-20mAs;
- Ultra-light weight at 105 kg;
- Ground Clearance allows for 75mm step up;
- Operation on uneven ground;
- Spare battery tray swap out in under a minute;

The unit uses FDA cleared digital image capture panels and software made by FujiFilm.

6) Substantial Equivalence Chart

Characteristic	DRX-Revolution Nano Mobile X-ray System K173924	Rover, K201488
Indications for Use:	The device is designed to perform radiographic x-ray examinations on pediatric and adult patients, in all patient treatment areas.	The device is designed to perform radiographic x-ray examinations on pediatric and adult patients, in all patient treatment areas. SAME
Configuration	Battery Operated Mobile System with digital x-ray panel and image acquisition computer	SAME
Generator	Maximum 4.8 kW @ 104 msec and 7.7 kW @ 13 msec 40 – 110 kV 0.2 – 20.0 mAs 30 – 70 mA	Maximum 4.8 kW @ 104 msec and 7.7 kW @ 13 msec of power 40 – 110 kV 0.2 – 20.0 mAs 30 – 70 mA SAME
Photos	DRX-Revolution Nano Mobile 	Rover  Very similar appearance and functionality
Digital X-ray Panel Supplied	Carestream DRX Family: K153142; K183245; K183474. 14” x 17” and 17” x 17” sizes.	Fujifilm FDR D-EVO Series, all FDA cleared K142003; K192932; 24x30cm, 14” x 17” and 17” x 17” sizes (CSL & GOS) Equivalent.
Software	Carestream DirectView	The Fuji FDX Console Advance DR-ID 300CL Software cleared in K192932
Panel Interface	Ethernet or Wi-Fi wireless	SAME

Characteristic	DRX-Revolution Nano Mobile X-ray System K173924	Rover, K201488
Operating System	Windows 7	Windows 10
Meets US Performance Standard	Meets all applicable requirements of 21 CFR 1020.30 and 21CFR 1020.31	SAME
Power Source	AC Line or Battery	SAME but the system has the additional feature of having a swap-out battery tray so the system does not have to limit use while plugged in to an AC line for charging.

7) **The technological characteristics, including design, materials, composition, and energy source, are substantially the same,** so there are no issues impacting safety and effectiveness.
Safety and Effectiveness, comparison to predicate device. The results of bench testing indicate that the new devices are as safe and effective as the predicate devices. Proper system operation is fully verified upon installation. We verified that the modified combination of components worked properly and produced diagnostic quality images as good as our predicate generator/panel combination.

8) **Summary of non-clinical testing**: Systems covering all generator/panel combinations were assembled and tested and found to be operating properly. Software was validated according to the FDA Guidance: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005.* Because the system uses Wi-Fi and Ethernet, we observed the recommendations contained in the FDA Guidance Document: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff Document Issued on: October 2, 2014*. The digital panel software employed was already reviewed by FDA. Labeling was developed and information provided in accordance with this FDA Guidance Document: *Pediatric Information for X-ray Imaging Device Premarket Notifications, Guidance for Industry and Food and Drug Administration Staff, November 2017.* Labeling also includes reference to the *Image Gently website (http://www.imagegently.org/).* Because the device contains wireless technology, we consulted *Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and FDA Staff, AUGUST 2013* and we incorporated those recommendations into our labeling.

The Rover Battery Mobile X-Ray Units have been tested to be in compliance with the following Standards:

US Performance Standard for Diagnostic X-Ray Systems: 21 CFR 1020.30 AND 21 CFR 1020.31.

IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012– Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance.

IEC60601-1-2:2014 Medical electrical equipment Collateral Standard: Electromagnetic compatibility Requirements and tests.

IEC 60601-1-3:2008 (Second Edition) + A1:2013 for use in conjunction with IEC 60601-1:2005 (Third Edition) + A1:2012

IEC 60601-1-6:2010 (Third Edition) + A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

IEC 60601-2-28:2017 for use in conjunction with 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 (or IEC 60601-1: 2012 reprint) Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis.

IEC 60601-2-54:2009, AMD1:2015 for use in conjunction with IEC 60601-1:2005, AMD1:2012 Particular Requirements For The Basic Safety And Essential Performance Of X-Ray Equipment for Radiography and Radioscopy.

9) **Summary of clinical testing:** Clinical testing was not required to establish substantial equivalence because all digital x-ray receptor panels have had previous FDA clearance.

10) **Conclusion: After analyzing bench and non-clinical tests, it is the conclusion of Micro-X that the new Rover Digital Diagnostic Mobile X-Ray Systems are as safe and effective as the predicate device, have few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.**