March 13, 2026

MARS Bioimaging Ltd.
℅ Melissa Dehass
Representative/Consultant
MEDIcept
200 Homer Ave,
ASHLAND, MA 01721

Re: K252249
Trade/Device Name: Extremity CT Imaging System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: February 11, 2026
Received: February 12, 2026

Dear Melissa Dehass:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252249

Device Name
Extremity CT Imaging System

Indications for Use *(Describe)*
The Extremity CT Imaging System is intended for x-ray computed tomography imaging of upper extremities of adult patients.

The device is intended to be operated in a professional healthcare environment by qualified and trained healthcare professionals only.

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."

K252249

510(k) Summary

DATE PREPARED
11 March 2026

MANUFACTURER AND 510(k) OWNER
MARS Bioimaging Ltd.
68 St. Asaph Street
Christchurch 8011
New Zealand
Official Contact: Homi Dalal, Head of Regulatory Affairs
Telephone: +64 21 1707631

REPRESENTATIVE /CONSULTANT
Melissa DeHass
MEDIcept
Telephone: (717)476-0702
Email: mdehass@medicept.com

DEVICE INFORMATION

Proprietary Name/Trade Name:	Extremity CT Imaging System
Regulation Name:	Computed Tomography X-Ray System
Regulation Number:	892.1750
Class:	II
Product Code:	JAK
Review Panel:	Radiology (OHT8)

PREDICATE DEVICE IDENTIFICATION

510(k) Number	Predicate Device Name / Manufacturer	Predicate/ Reference
K160723	OnSight 3D Extremity System (Carestream Health, Inc.)	Predicate
K233657	NAEOTOM Alpha (Siemens Medical Systems)	Reference

The predicate and reference devices have not been subject to a design related recall.

DEVICE DESCRIPTION

The Extremity CT Imaging System™ is a computed tomography x-ray system designed for imaging of the upper limb. The device acquires volumetric spectral CT imaging using helical rotation of a single x-ray source and photon counting detectors with the limb stationary throughout the scan.

The use of photon-counting technology in the Medipix X-ray detector enables the scanner to detect individual X-ray photons with greater precision in comparison to conventional CT scanners, which typically rely on energy-integrating detectors. By counting the number of

photons that pass through the body part and measuring their energy levels, the scanner can capture more detailed information about the composition of the tissues being imaged.

The Extremity CT Imaging System is intended for use in professional healthcare facility environments, excluding oxygen-rich environments, by trained medical professionals The imaging data produced by the system is intended to support diagnosis, treatment planning, and monitoring of patient conditions. It is to be noted however that actual diagnosis is not performed using any part of this software. The images produced by the system serve as a valuable tool for assessing pathologies related to the hand and wrist of adult patients

The device is meant for prescription use only by qualified and trained medical professionals.

The scanner is compact, with a small footprint and an entry port of diameter 12 cm (4.8 inches) ideally suited for imaging the hand and wrist. The scanner is mobile but must be used in a stationary position.

The system is designed to provide a streamlined workflow from patient scanning to the delivery of high-quality images, to ultimately support patients' diagnosis. Once the data has been processed within the scanner's computer, it is accessed from the Workstation using the specialized image processing software, MARS Vision, for post-processing. This stage involves advanced image manipulation, including multiplanar reformats (MPR) and 3D visualization (direct volume rendering and maximum intensity projection). Following the data review and post-processing in MARS Vision, high-quality images in DICOM format are created and uploaded to the facility's Picture Archiving and Communication System (PACS) system, where they are securely stored and made available for review.

Overall, the device description for the Extremity CT Imaging System™ above addresses recommendations outlined in the device-specific guidance documents and meets requirements appropriate for the device classification and applicable special controls.

INDICATIONS FOR USE

The Extremity CT Imaging System is intended for x-ray computed tomography imaging of upper extremities of adult patients.

The device is intended to be operated in a professional healthcare environment by qualified and trained healthcare professionals only.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Mars Bioimaging believes that the Extremity CT Imaging System is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has the same intended use/indications for use as the predicate device as both devices are intended to be used as x-ray computed tomography for imaging of upper extremities in adult patients..

The Extremity CT Imaging System and the predicate device are based on the same or similar technological characteristics, as outlined in the table below.

- Both systems utilize the same or similar power generator.
- Both systems have the same or similar scanner and the same method for scanning acquisition.
- Both systems connect to the network for data display and transmission in the same or similar manner.
- Both systems offer the same or similar image analysis and reconstruction.

Characteristic	**Subject Device Extremity CT Imaging System™**	**Predicate Device Carestream OnSight 3D Extremity System K160723**	**Equivalence Comparison**
Intended Use/Indications for Use	The Extremity Imaging System is intended for x-ray computed tomography imaging of upper extremities of adult patients	The device is intended to be used for x-ray computed tomography and projection x-ray imaging of upper and lower extremities of adult and pediatric patients aged 12 and over.	**Similar**
X-ray source	Low power, x-ray tube Fixed anode. Single source. Tube voltage: 60 to 120 kVp Tube current: 0.01 mA – 0.35 mA	Low power x-ray tube. Fixed anode Three sources. Tube voltage 50 to 90 kVp Tube current: 2 – 10 mA	**Similar**
Target Angle	20°	20°	**Same**
Focal spot	Fixed. Small (0.07 mm)	Fixed. Small (0.50 mm)	**Similar**
Collimator type	Fixed to match active area of detector	Fixed to match active area of detector	**Same**
Exposure type	Continuous exposure	Pulsed exposure	**Different, does not raise new questions of safety and effectiveness**

Characteristic	Subject Device Extremity CT Imaging System™	Predicate Device Carestream OnSight 3D Extremity System K160723	Equivalence Comparison
Energy settings (kV)	Scan acquired using one pre-programmed energy setting. Information captured in multiple energy bins, to provide spectral data – see detector technology)	Scan acquired using one pre-programmed energy setting (eg. 90 kV). No spectral data provided.	**Similar**
Detector technology	Photon counting detector with CdTe sensor and Medipix 3RX readout technology. Direct conversion of photon energies into electrical signal.	Flat panel detector with amorphous silicon (a-Si:H) sensor layer. Indirect conversion of photon energies into electrical signal.	**Different, does not raise new questions of safety and effectiveness**
Detector active area	128 x 1536 pixels Pixel pitch 110mm	1782 x 2166 pixels Pixel pitch 139mm	**Different, does not raise new questions of safety and effectiveness**
Localization	Scout scan	Scout scan	**Same**
Principles of operation	Acquires projection images sequentially as the x-ray source and detector rotate around the limb (typically 373 projections per rotation) Covers the region of interest by helical rotation and z-axis translation of the x-ray tube and detector. The scanner cabinet and patient remain stationary throughout the scan.	Acquires projection images sequentially as the x-ray source and detector rotate around the limb (typically 600 projections per rotation) Covers the region of interest by a single rotation of the x-ray tube and detector. The scanner cabinet and patient remain stationary throughout the scan.	**Similar**
Weightbearing capability/Gantry tilt	No	Upper and lower extremity imaging	**Different, does not raise new questions of safety and**

Characteristic	Subject Device Extremity CT Imaging System™	Predicate Device Carestream OnSight 3D Extremity System K160723	Equivalence Comparison
			effectiveness
Tube modulation / AEC	No	Yes. Smart Dose. (User selected)	**Different, does not raise new questions of safety and effectiveness**
Dose check	System includes dose notifications and alerts based on pre programmed thresholds.	System includes dose notifications and alerts based on pre programmed thresholds.	**Same**
Emergency stop buttons	Available at gantry and control panel	Available at gantry and control panel	**Same**
Power requirements	120 V or 230 V	120 V or 230 V	**Same**
Scanner dimensions	Small footprint. 748mm x 1120 mm	Small footprint. 1524mm x 1830mm	**Similar**
Gantry Bore Size	Small	Small	**Similar**
Patient positioning accessories	Static arm support manually aligned in the gantry Immobilization strapping applied (single use fabric with re-usable anchors) Patient sat in chair (Standard off-the-shelf office chair, not provided by manufacturer)	Static arm support, manually aligned in gantry. Immobilization strapping applied (re-usable) Patient sat in chair (Chair provided by manufacturer)	**Similar**
Radiation shielding	Internal shielding in scanner cabinet	Internal shielding in scanner cabinet and additional lead curtain.	**Similar**
Portability	Scanner mounted on roll wheels	Scanner mounted on roll wheels	**Same**

Characteristic	Subject Device Extremity CT Imaging System™	Predicate Device Carestream OnSight 3D Extremity System K160723	Equivalence Comparison
Reconstruction method	Iterative reconstruction (statistical, non-linear)	Iterative reconstruction (algebraic, linear) Or Filtered back projection	**Similar**
Reconstructed images	Cross-sectional CT imaging in Hounsfield units (HU)	Cross sectional CT imaging in Hounsfield units (HU).	**Similar**
Reconstructed voxel size	0.09mm - 0.5mm User selected	0.26mm – 0.52 mm User selected	**Similar**
Metal artifact reduction algorithms	Not required	Optional	**Different, does not raise new questions of safety and effectiveness**
Image visualization platform	Yes (MARS Vision), Microsoft Windows based operating system	Yes (Image View), Microsoft Windows based operating system.	**Same**
Window width / window level adjustment	Yes	Yes	**Same**
Multiplanar reformats	Multiplanar reformats include axial, coronal, sagittal and oblique planes	Multiplanar reformats including axial, coronal, sagittal and oblique planes	**Same**
3D Volume rendering	Yes	Yes	**Same**
Network connections	Ethernet connections. PACS connectivity.	Ethernet connections. RIS and PACS connectivity.	**Similar**
Data exports	DICOM images and structured dose report exported directly to site PACS	DICOM images and structured dose report exported directly to site PACS	**Same**
DICOM conformance	Yes	Yes	**Same**

Characteristic	Subject Device Extremity CT Imaging System™	Predicate Device Carestream OnSight 3D Extremity System K160723	Equivalence Comparison

Based on the testing performed, including software and performance, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate device.

SUMMARY OF NON-CLINICAL TESTING
The Extremity CT Imaging System conforms to the FDA Guidance Document 'Medical X-Ray Imaging Devices Conformance with IEC Standards: Guidance for Industry and Food and Administration Staff' and applicable clauses of the applied Recognized Consensus Standards pertinent to Registration Number 892.1750, Product Code JAK.

Biocompatibility: Biocompatibility was assessed per ISO 10993-1: 2018 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management system,* and in line with FDA Final Guidance on Use of International Standard ISO 10993-1 (Biocompatibility).

Performance Testing: Performance testing was conducted to evaluate the performance of the Extremity CT Imaging System in comparison to the predicate OnSight 3D Extremity System (K160723), using the following:

- Water Phantom QA
  - Uniformity
  - Signal to Noise Ratio
  - Noise
- Wire Phantom QA
  - Modulation transfer function
  - Effective slice thickness
- Contrast Resolution
- High-z materials
- Direct dose comparison

The performance of the Extremity CT imaging system was also characterized through the following tests:

- Detector characterization
- Environmental conditions testing
- Slice Sensitivity Profile
- Noise Power Spectrum
- Pulse pile-up

- Spectral resolution
- Count rate vs Current and Linearity of radiation output
- Deterministic Effects
- Focal Spot to Skin Distance
- Stray radiation
- Beam quality (half-value layer) and filtration
- Dose Measurements including:
    - $CTDI_{air}$
    - $CTDI_{100}$
    - Reproducibility
    - Geometric efficiency

The results of these tests indicate that the Extremity CT Imaging System is substantially equivalent to the predicate and reference devices.

SUMMARY OF CLINICAL TESTING
Visual grading studies were conducted in which representative hand, wrist, finger and thumb MSK diagnostic images, reviewed by American Board Certified Radiologists, were obtained using the subject device and it was confirmed that the reconstructed images using the subject device were of diagnostic quality.

CONCLUSION
Based on the testing performed, including non-clinical and clinical performance testing, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate device. The similar indications for use, technological characteristics, and performance characteristics for the proposed Extremity CT Imaging System are assessed to be substantially equivalent to the predicate device.