May 16, 2025

Medicatech USA Inc.
% Theodor Gillebaard
Operations
50 Maxwell
IRVINE, CA 92618

Re: K242731
Trade/Device Name: MasteRad MiniX Mobile Digital Imaging System (Mini-X)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA, OXO
Dated: April 16, 2025
Received: April 16, 2025

Dear Theodor Gillebaard:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K242731

Device Name

MasteRad MiniX Mobile Digital Imaging System (Mini-X)

Indications for Use *(Describe)*

Mini-X is intended for use by qualified/trained medical professionals who fully understand the safety information, emergency procedures, and the device's capabilities and function. The device provides fluoroscopic imaging and is used for guidance and visualization during diagnostic radiography and surgical procedures of the extremities. The device will be used in healthcare facilities inside and outside the hospital, using various methods for the extremities on all patients except neonates (birth to one month) within the limits of the device. Applications can be performed with the patient sitting, standing, or lying in a prone or supine position. The system is not intended for mammography applications. (Rx 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.

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510(k) #: K242731

510(k) Summary

Prepared on:

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Medicatech USA Inc.
Applicant Address	50 Maxwell Irvine CA 92618 United States
Applicant Contact Telephone	949-463-5218
Applicant Contact	Mr. Theodor Gillebaard
Applicant Contact Email	theodor@medicatechusa.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	MasteRad MiniX Mobile Digital Imaging System (Mini-X)
Common Name	Image-intensified fluoroscopic x-ray system
Classification Name	Image-intensified fluoroscopic x-ray system
Regulation Number	892.1650
Product Code(s)	OWB, JAA, OXO

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K212523	VFSS PRO Mobile Digital Imaging System	OWB
K210469	Insight Agile DRF	JAA
K212557	Virtual C DRF-NEO Digital Imaging System	OWB

Device Description Summary

21 CFR 807.92(a)(4)

The Mini-X system, a unique mobile imaging system, can acquire, process, and display fluoroscopic images. Its portability allows for easy positioning within a room and movement from room to room within a facility, facilitating on-demand fluoroscopic examinations. The system's innovative design incorporates a low-powered mono-block generator and a dynamic flat-panel detector, enabling it to be powered through a single-phase 120VAC power outlet.

The Insight Enhanced™ DRF Digital Imaging System, a cutting-edge tool for healthcare professionals, offers full control over the imaging chain. It empowers the operator to view and enhance high-definition fluoroscopy images up to 30 fps, bringing out diagnostic details that are challenging or impossible to see using conventional imaging techniques. The system's versatility is demonstrated by its ability to store images locally for short-term storage, produce hardcopy images with a laser printer, or send images over a network for longer-term storage. Its primary components, including a dynamic flat panel detector, monitors, and an image processor PC, underscore its comprehensive and advanced capabilities.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Mini-X is intended for use by qualified/trained medical professionals who fully understand the safety information, emergency procedures, and the device's capabilities and function. The device provides fluoroscopic imaging and is used for guidance and visualization during diagnostic radiography and surgical procedures of the extremities. The device will be used in healthcare facilities inside and outside the hospital, using various methods for the extremities on all patients except neonates (birth to one month) within

the limits of the device. Applications can be performed with the patient sitting, standing, or lying in a prone or supine position. The system is not intended for mammography applications. (Rx Only)

Indications for Use Comparison 21 CFR 807.92(a)(5)

Comparison with Predicate Device: The Mini-X and the predicate device (VFSS Pro Mobile Digital Imaging System, (K212523) share similar indications for use, as both are designed for real-time fluoroscopic imaging to visualize internal body structures and guide medical procedures. Both devices are intended for use by trained professionals in healthcare settings for diagnostic and interventional procedures. The Mini-X specifically targets imaging of the extremities, while the predicate device has a broader application, including general fluoroscopic imaging. The Mini-X explicitly excludes neonates (birth to one month) and mammography applications, whereas the predicate device does not specify these exclusions but is similarly not intended for mammography. Despite these differences, the core intended use-providing real-time fluoroscopic imaging for guidance during medical procedures-remains unchanged. The Mini-X's focus on extremities and exclusion of neonates does not alter the fundamental purpose or clinical application compared to the predicate, ensuring substantial equivalence in intended use.

Technological Comparison 21 CFR 807.92(a)(6)

Technological Comparison
The Mini-X and the predicate device (VFSS Pro Mobile Digital Imaging System, K212523) share key technological characteristics, including the use of flat-panel detectors for fluoroscopic imaging, mobile design for use in healthcare facilities, and digital imaging chains for real-time visualization. Both devices are classified under 21 CFR892.1650, with product codes OWB, JAA, and OXO, and are intended for similar clinical applications.

Similarities:
Detector Technology: Both devices utilize flat-panel detectors with Indium Zinc Gallium Oxide (IZGO) substrates, offering lower noise and greater radiation exposure tolerance compared to traditional a-Si TFT detectors.
Imaging Chain: Both systems incorporate a digital imaging chain, including dynamic flat-panel detectors, image processors, and monitors, to acquire and display high-definition fluoroscopic images at up to 30fps.
Portability: Both are mobile fluoroscopic systems designed for easy positioning and movement within healthcare facilities.
Software: The Mini-X uses a software application previously cleared under K210496, similar to the predicate's imaging chain components, ensuring comparable image processing and display capabilities.

Differences:
Source-to-Image Distance (SID): The Mini-X has a fixed SID of 50 cm, compared to the predicate's 100 cm. This reduced SID compensates for the Mini-X's lower-powered X-ray generator by maintaining adequate detector entrance dose, ensuring equivalent image quality.
X-ray Generator: The Mini-X employs a lower-powered mono-block generator, enabling operation via a standard 120VAC outlet, unlike the predicate's higher-powered generator. The reduced SID mitigates the impact of the lower power on imaging performance.
Spatial Resolution: The Mini-X offers twice the spatial resolution capability of the predicate, enhancing diagnostic detail for extremity imaging.
Detector Model: The Mini-X uses the DRTECH EXPD 2430P as an alternative dynamic detector, previously cleared under K212557 (Virtual C DRF-NEO), while the predicate uses a different detector model. Both detectors share similar IZGO technology and performance characteristics.
Intended Applications: The Mini-X is optimized for extremity imaging, whereas the predicate supports broader fluoroscopic applications. This specialization does not affect the core technological function of real-time fluoroscopic imaging.
Impact of Differences: The technological differences-fixed 50 cm SID, lower-powered generator, and enhanced spatial resolution--do not raise new safety or effectiveness concerns. The reduced SID compensates for the lower-powered generator, maintaining comparable detector entrance doses and image quality, as demonstrated in bench testing. The DRTECH EXPD 2430P detector's prior clearance (K212557) and similar IZGO technology ensure equivalence in imaging performance. The Mini-X's higher spatial resolution enhances its capability for detailed extremity imaging without altering the fundamental imaging function. Bench testing, including phantom image comparisons and dose analysis, confirmed that the Mini-X achieves equivalent imaging performance to the predicate. Compliance with standards such as IEC 60601-1-3, IEC 60601-2-54, IEC 60601-2-43, and 21 CFR 1020.32, as verified in performance testing, further supports the device's safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Bench testing was performed on the subject device to assess its substantial equivalence regarding image quality. Both detectors were integrated with the Source-Ray generator. Phantom images were acquired with the subject device and compared to the predicate device. These images and the doses used to acquire them were analyzed and compared. In conclusion, the tests demonstrated substantial equivalence to the predicate device regarding imaging performance.

Imaging Engineering performed additional bench testing on the Mini-X Mobile system to determine whether it complies with IEC

60601-1-3:2008+A1:2013, IEC 60601-2-54:2022, IEC 60601-2-43:2022, and 21 CFR 1020.32. The system passed all electrical, mechanical, and radiation safety testing. EMC and Electrical Safety performance for the DRTECH digital receptor panel had previously been submitted to the FDA in K212557.

The software has been written and validated according to the FDA Software Guidance: Content of Premarket Submissions for Device Software Functions Document issued on June 14, 2023. Cybersecurity concerns have been addressed following the content of Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (September 27, 2023).

The Mini-X mobile, the subject device, is substantially equivalent to the predicate (K212523). Its intended use, design principle, and applicable standards are identical to the predicate device's. The performance test and non-clinical consideration results demonstrate that these differences do not raise any new questions of safety and effectiveness. Therefore, the sponsor believes the subject device appears as safe and effective as the predicate device.