June 23, 2022

Konica Minolta, Inc.
% Jan Maniscalco
Director of QA/RA
Konica Minolta Healthcare Americas, Inc.
411 Newark-Pompton Turnpike
WAYNE NJ 07470

Re: K220993
Trade/Device Name: Ultrasound System SONIMAGE MX1
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: March 31, 2022
Received: April 4, 2022

Dear Jan Maniscalco:

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

Michael D. O'Hara, Ph.D.
Deputy Director
DHT 8C: Division of Radiological Imaging
and Radiation Therapy Devices
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)*
K220993

Device Name
Ultrasound System SONIMAGE MX1

Indications for Use *(Describe)*
The Ultrasound System SONIMAGE MX1 and its transducers are products designed to collect ultrasonic image data of the human body for diagnostic purposes. The system employs the ultrasonic pulse-echo method to visualize the anatomic structures, characteristics, and dynamics of the human body, and using an image display, Doppler display and/or Doppler sound, offers a procedure applied to the human body for medical diagnosis or examination.

The range of intended clinical applications is same as other conventional ultrasound imaging systems for general purpose, such as small parts, abdomen, musculoskeletal, cardiac, and peripheral vascular.

This device is intended for use in healthcare facilities, such as health clinics and hospitals.

Intended user for the device are physician, sonographer, and other trained qualified healthcare professionals.

Modes of operation include B-mode, M-mode, PWD-mode, CWD-mode, Color Doppler-mode, Power Doppler-mode, and their Combined mode.

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

K220993

Company: KONICA MINOLTA, INC.
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Quality Assurance Operations, Healthcare Business Unit
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Date Prepared: June 22, 2022

Device Name:	Ultrasound System SONIMAGE MX1	
Common Name:	Diagnostic Ultrasound System and Transducers	
Regulation Name(s):	Ultrasonic Pulsed Doppler Imaging System	(21 CFR 892.1550)
	Ultrasonic Pulsed Echo Imaging System	(21 CFR 892.1560)
	Diagnostic Ultrasound Transducer	(21 CFR 892.1570)
Regulatory Class:	Class II	
Product Code(s):	IYN, IYO, ITX	

Predicate Device:	K180084 - Ultrasound System SONIMAGE MX1
Reference Device:	K182153 - Ultrasound System SONIMAGE HS1

Device Description

The Ultrasound System SONIMAGE MX1 is a portable diagnostic ultrasound system for general purposes. The system provides ultrasound imaging information such as used for the purpose of diagnosing the human body, which visually represents the internal geometry, characteristics and dynamics of the human body, and transmits / receives ultrasound waves to obtain image data of the visual representation.

This system provides ultrasound images in conventional modes of B-mode, M-mode, Color Doppler-mode, Power Doppler-mode, PW Doppler-mode and CW Doppler-mode.

The optional items are available, such as a Cradle, a Three port probe unit, an Additional Battery, and a Foot Switch with dual/triple pedals.

The system can be connected to LAN through the wired Ethernet and, is also capable of wireless LAN with the OTS USB-WiFi adapter supporting security of WPA/WPA2 and WEP.

This system conforms to Real Time Display of Thermal and Mechanical Output Indices on Diagnostic Ultrasound Equipment (Track 3). Transducers have their own characteristic applications and are brought into contact with the body surface.

Indications for Use

The Ultrasound System SONIMAGE MX1 and its transducers are products designed to collect ultrasonic image data of the human body for diagnostic purposes. The system employs the ultrasonic pulse-echo method to visualize the anatomic structures, characteristics, and dynamics of the human body, and using an image display, Doppler display and/or Doppler sound, offers a procedure applied to the human body for medical diagnosis or examination.

The range of intended clinical applications is same as other conventional ultrasound imaging systems for general purpose, such as small parts, abdomen, musculoskeletal, cardiac, and peripheral vascular.

This device is intended for use in healthcare facilities, such as health clinics and hospitals.

Intended user for the device are physician, sonographer, and other trained qualified healthcare professionals.

Modes of operation include B-mode, M-mode, PWD-mode, CWD-mode, Color Doppler-mode, Power Doppler-mode, and their Combined mode.

Comparison Table

The comparison to the predicate devices was summarized in the table blow.

	Subject Device	Predicate Device
Device Name	**Ultrasound System SONIMAGE MX1**	**Ultrasound System SONIMAGE MX1**
510(K) #	**K220993**	**K180084**
Indications for Use	The Ultrasound System SONIMAGE MX1 and its transducers are products designed to collect ultrasonic image data of the human body for diagnostic purposes. The system employs the ultrasonic pulse-echo method to visualize the anatomic structures, characteristics, and dynamics of the human body, and using an image display, Doppler display and/or Doppler sound, offers a procedure applied to the human body for medical diagnosis or examination. The range of intended clinical applications is same as other conventional ultrasound imaging systems for general purpose, such as small parts, abdomen, musculoskeletal, cardiac, and peripheral vascular. This device is intended for use in healthcare facilities, such as health clinics and hospitals. Intended user for the device are physician, sonographer, and other trained qualified healthcare professionals. Modes of operation include B-mode, M-mode, PWD-mode, CWD-mode, Color Doppler-mode, Power Doppler-mode, and their Combined mode.	The Ultrasound System SONIMAGE MX1 and its transducers are products designed to collect ultrasonic image data of the human body for diagnostic purposes. The system employs the ultrasonic pulse-echo method to visualize the anatomic structures, characteristics, and dynamics of the human body, and using an image display, Doppler display and/or Doppler sound, offers a procedure applied to the human body for medical diagnosis or examination. The range of intended clinical applications is same as other conventional ultrasound imaging systems for general purpose, such as small parts, abdomen, musculoskeletal, and peripheral vascular. *The transducer functions tables include; B-mode, PWD-mode, Color Doppler-mode, Power Doppler-mode, and their Combined mode.
510(k) Track	Track 3	Track 3
Scanning Method	Electronic Linear Electronic Convex Electronic Sector	Electronic Linear Electronic Convex
Modes of operation	・ B (2D)-mode ・ M-mode	・ B (2D)-mode ・ Color Flow-mode

	Subject Device	Predicate Device
Device Name	**Ultrasound System SONIMAGE MX1**	**Ultrasound System SONIMAGE MX1**
510(K) #	**K220993**	**K180084**
	w/Anatomical M mode ・ Color Flow-mode ・ Power Doppler-mode ・ PW Doppler-mode ・ CW Doppler-mode ・ Combination (BM, BD, Bc, BcD)	・ Power Doppler-mode ・ PW Doppler-mode ・ Combination (BD, Bc, BcD)
Transducer	・ CONVEX PROBE C5-2 ・ CONVEX PROBE MC10-3 ・ LINEAR PROBE L14-4 ・ LINEAR PROBE L11-3 ・ LINEAR PROBE L18-4 ・ LINEAR PROBE HL18-4 ・ SECTOR PROBE S4-2	・ CONVEX PROBE C5-2 ・ CONVEX PROBE MC10-3 ・ LINEAR PROBE L14-4 ・ LINEAR PROBE L11-3
Function	・ Needle Visualization (Simple Needle Visualization) ・ Auto IMT ・ Wireless LAN ・ RA Workflow ・ Anti -Virus ・ DICOM Storage ・ DICOM Worklist ・ Internal Storage Encryption ・ Library ・ Shared Library ・ ECG Function ・ Vascular NAVI ・ Image improvement (iXRET) ・ Camera Function ・ Direct Recording	・ Needle Visualization (Simple Needle Visualization) ・ Auto IMT ・ Wireless LAN ・ RA Workflow ・ Anti -Virus ・ DICOM Storage ・ DICOM Worklist ・ Library
Optional kit	Biopsy Adapters Acoustic standoff Reference Signal Unit (ECG Trigger)	Biopsy Adapters Acoustic standoff

The following technological differences exist between the subject and predicate devices:

- Addition of M-mode and CW Doppler-mode (K182153).
- Addition of Transducers: Linear probe L18-4 (K142197), HL18-4 (K162065) and Sector probe S4-2 (K151060).
- ECG Function, which was already cleared on the reference device (K151060).

- Shared Library Function: To save the still images and video/audio clips in the shared folder.
- Vascular NAVI: To simplify vascular ultrasound by adjusted optimized parameters for blood flow evaluation.
- iXRET (EXtended Resolution Enhancement Technology): To improve resolution while maintaining frame rate.
- Camera Function: To simultaneously display ultrasonic images and images from a USB-connected WEB Camera.
- Direct Recording Function: To save the still images and clip files to external storage media.

Performance Data

The Ultrasound System SONIMAGE MX1 is designed to comply with the following standards:

- AAMI ANSI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text); Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2 Edition 4.0 2014-02; Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION; Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-2-37 Edition 2.1 2015; Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 62359 Edition 2.1 2017-09 CONSOLIDATED VERSION; Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields
- NEMA UD 2-2004 (R2009); Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION; Medical device software - Software life cycle processes

FDA guidance document *"Marketing Clearance of Diagnostic Ultrasound Systems and Transducers"*, issued on June 27, 2019 was referenced for this submission, along with *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document"* issued on May 11, 2005. Additionally, cybersecurity documentation, per the FDA guidance document *"Content of Premarket Submissions for Management of Cybersecurity in Medical Devices"* issued on October 18, 2018 was also included in this submission, along with *"Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices"*, issued on September 6, 2017.

Risk Analysis and verification and validation activities demonstrate that the established specifications for these devices have been met. The results of risk management did not require clinical studies to demonstrate the substantial equivalency of the proposed device.

Conclusion

The Ultrasound System SONIMAGE MX1 has the same intended use and the cardiac extended indications for use, technological characteristics, and principle of operations. The technological differences raised no new issues of safety or effectiveness as compared to its predicate device (K180084). Performance tests demonstrate that the Ultrasound System SONIMAGE MX1 performs according to specifications and functions as intended.

Therefore, as for our conclusion, the Ultrasound System SONIMAGE MX1 is substantially equivalent to the predicate device and presents no new questions of safety or effectiveness.