Konica Minolta, Inc.
% Russell D. Munves
US Agent
STORCH AMINI PC
140 East 45th Street, 25th Floor
NEW YORK NY 10017

February 8, 2018

Re: K180084
Trade/Device Name: Ultrasound System SONIMAGE MX1
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: January 10, 2018
Received: January 11, 2018

Dear Mr. Munves:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*

K180084

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, and peripheral vascular.

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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System: **Ultrasound System SONIMAGE MX1**

Transducer: _____

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N		N		N	Note1	
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Note2)	N		N		N	Note1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N		N		N	Note1	
	Musculo-skeletal (Superficial)	N		N		N	Note1	
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N		N		N	Note1	
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Combined mode BD (B + Pulse Doppler) and BcD (B Color Doppler + Pulse Doppler)

Note 2: General small organ includes thyroid and breast

Prescription Use Only (Per 21 CFR801.109)

System: **Ultrasound System SONIMAGE MX1**
Transducer: **C5-2**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N		N		N	Note1	
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Note2)	N		N		N	Note1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
Note 1: Combined mode BD (B + Pulse Doppler) and BcD (B Color Doppler + Pulse Doppler)
Note 2: General small organ

Prescription Use Only (Per 21 CFR801.109)

System: **Ultrasound System SONIMAGE MX1**
Transducer: **L14-4**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Note2)	N		N		N	Note1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N		N		N	Note1	
	Musculo-skeletal (Superficial)	N		N		N	Note1	
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N		N		N	Note1	
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
Note 1: Combined mode BD (B + Pulse Doppler) and BcD (B Color Doppler + Pulse Doppler)
Note 2: General small organ includes thyroid and breast

Prescription Use Only (Per 21 CFR801.109)

System: **Ultrasound System SONIMAGE MX1**

Transducer: **L11-3**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Note2)	N		N		N	Note1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N		N		N	Note1	
	Musculo-skeletal (Superficial)	N		N		N	Note1	
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N		N		N	Note1	
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Combined mode BD (B + Pulse Doppler) and BcD (B Color Doppler + Pulse Doppler)

Note 2: General small organ includes thyroid and breast

Prescription Use Only (Per 21 CFR801.109)

System: **Ultrasound System SONIMAGE MX1**
Transducer: **MC10-3**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Note2)	N		N		N	Note1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N		N		N	Note1	
	Musculo-skeletal (Superficial)	N		N		N	Note1	
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N		N		N	Note1	
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
Note 1: Combined mode BD (B + Pulse Doppler) and BcD (B Color Doppler + Pulse Doppler)
Note 2: General small organ

Prescription Use Only (Per 21 CFR801.109)

510(k) Summary

Submitter's Name:	KONICA MINOLTA, INC.
Address:	1 Sakura-machi, Hino-shi, 191-8511 Japan
Contact:	Tsutomu Fukui
Telephone:	+81 42 589 8429
Date:	January 10, 2018
Trade Name:	Ultrasound System SONIMAGE MX1
Model No:	SONIMAGE MX1
Common Name:	Ultrasound Imaging System
Classification 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)
Classification Number(s):	90-IYN; 90-IYO; 90-ITX
Regulatory Class:	Class II
Predicate Device(s):	K162065 – Ultrasound System SONIMAGE HS1, Konica Minolta, Inc.

Device Description:

The Ultrasound System SONIMAGE MX1 is a portable 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, Color Doppler-mode, and PW Doppler-mode.

The optional items are available, such as a Cradle, an Additional Battery, a Three port probe unit, 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.

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

AAMI / ANSI ES 60601-1: 2005 and A1: 2012, C1:2009 and A2:2010;
IEC 60601-1-6: 2010;
IEC 60601-1-2: 2007;
IEC 60601-2-37: 2007;
IEC 62304: 2006;
NEMA UD 2-2004; NEMA UD 3-2004;

Intended 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 the predicate device, such as small parts, abdomen, musculoskeletal, and peripheral vascular.

This system is contraindicated for ophthalmological exams or exams in which ultrasonic waves may pass through the eyeballs.

This system is NOT designed for use in direct contact to central nerves and cardiac systems.

The system should not be used by persons other than fully qualified and certified medical personnel.

Summary of Technological Characteristics
Compared to Predicate Device:

The proposed Ultrasound System SONIMAGE MX1 employs the same fundamental scientific technologies as the primary predicate device (K162065). The summary of comparisons of technological characteristics for the proposed device and the predicate systems are provided as follows;

Intended Use

The intended use of the proposed device is essentially the same as the conventional ultrasound diagnostic system for general purpose, the same as the indication for use of the predicate device (K162065).

Operating Principle and designing

The proposed and predicate systems transmit ultrasonic energy into patients by using same transducers, then perform post processing of received echoes to generate on-screen display of anatomic structures and dynamics of the human body. The form of the system is different but both systems are designed to be transportable with battery operation. These operating principle and designing are the same as the predicate device.

The proposed system doesn't support a conventional M mode but supports the same operating modes and display format as those supported by the predicate system. The both systems support same fundamental measurement functions for anatomic structures, internal geometry, characteristics and dynamics of the human body.

Non-clinical test

The geometric accuracy verification in B-mode and the accuracy verification of the position and the velocity for Color Doppler-mode and PW Doppler-mode, and the time for PW Doppler-mode are comprehensively tested as Bench-tests with successful results.
The proposed system and the predicate systems do not have a quantitative claims of sensitivity regarding Color Doppler-mode and PW Doppler-mode.

All of the verification activities, including as required by the risk analysis, for the proposed system was performed and the results demonstrated that the predetermined acceptance criteria were met.

Safety

The system is in conformance with the standards described above, which are same standards as those of the primary predicate device (K162065). The both systems conform to real time display of thermal and mechanical output indices under Track 3.

Biocompatibility

No transducer is newly introduced in this application. The all patient contact materials of human body surface are identical to those of the predicate, and then both systems achieve same acceptance level for biocompatibility.

Conclusion:

The clinical studies are not required to support substantial equivalence for these conventional ultrasound diagnostic equipment. In addition to that, as discussed in the above technological comparison, the technological characteristics of the Ultrasound System SONIMAGE MX1 are deemed to be substantially equivalent to the aforementioned predicate devices that have already been cleared for USA distribution with 510(k) premarket notification.