KONICA MINOLTA, Inc.
℅ Mr. Russell Munves
Storch Amini PC
140 East 45th Street, 25th floor
NEW YORK, NY 10017

September 6, 2018

Re: K182153
Trade/Device Name: Ultrasound System SONIMAGE HS1
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, IYN, ITX
Dated: August 7, 2018
Received: August 8, 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. 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.

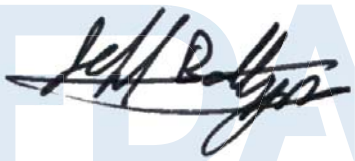
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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 A. 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)*

K182153

Device Name

Ultrasound System SONIMAGE HS1

Indications for Use *(Describe)*

The Ultrasound System SONIMAGE HS1 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, obstetrics, gynecology, musculoskeletal (soft tissue), peripheral vascular, and Cardiac.

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 HS1**

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	P	P	P		P	Note1	Note2
	Abdominal	P	P	P	P	P	Note1	Note2,4
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Note3)	P	P	P		P	Note1	Note2, 5
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	P	P	P		P	Note1	Note2
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P	P	P		P	Note1	Note2, 5
	Musculo-skeletal (Superficial)	P	P	P		P	Note1	Note2, 5
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	P	P	P	P	P	Note1	Note2,4
	Cardiac Pediatric	P	P	P	P	P	Note1	Note2,4
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note1	Note2, 5
	Other (Specify)							

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

Note 1: Combined mode BM (B + M), BD (B + Pulse Doppler), BcMc (Color Doppler + M Color Doppler) and BcD (B Color Doppler + Pulse Doppler)

Note 2: Other mode Mc (M Color Mode)

Note 3: Small organ includes thyroid and breast

Note 4: Other mode CF-TDI(Color Flow - Tissue Doppler Imaging) and PW-TDI(Pulse Doppler - Tissue Doppler Imaging)

Note 5: Other mode Elastography

Prescription Use Only (Per 21 CFR801.109)

System: **Ultrasound System SONIMAGE HS1**

Transducer: **L18-4**

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 (Note3)	P	P	P		P	Note1	Note2, 4
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P	P	P		P	Note1	Note2, 4
	Musculo-skeletal (Superficial)	P	P	P		P	Note1	Note2, 4
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note1	Note2, 4
	Other (Specify)							

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

Note 1: Combined mode BM (B + M), BD (B + Pulse Doppler), BcMc (Color Doppler + M Color Doppler) and BcD (B Color Doppler + Pulse Doppler)

Note 2: Other mode Mc (M Color Mode)

Note 3: Small organ includes thyroid and breast

Note 4: Other mode Elastography

Prescription Use Only (Per 21 CFR801.109)

System: **Ultrasound System SONIMAGE HS1**

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	P	P	P		P	Note1	Note2
	Abdominal	P	P	P		P	Note1	Note2
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	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 BM (B + M), BD (B + Pulse Doppler), BcMc (Color Doppler + M Color Doppler) and BcD (B Color Doppler + Pulse Doppler)

Note 2: Other mode Mc (M Color Mode)

Prescription Use Only (Per 21 CFR801.109)

System: **Ultrasound System SONIMAGE HS1**

Transducer: **S4-2**

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	P	P	P	P	P	Note1	Note2,3
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	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	P	P	P	P	P	Note1	Note2,3
	Cardiac Pediatric	P	P	P	P	P	Note1	Note2,3
	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 BM (B + M), BD (B + Pulse Doppler), BcMc (Color Doppler + M Color Doppler) and BcD (B Color Doppler + Pulse Doppler)

Note 2: Other mode Mc (M Color Mode)

Note 3: Other mode CF-TDI(Color Flow - Tissue Doppler Imaging) and PW-TDI(Pulse Doppler - Tissue Doppler Imaging)

Prescription Use Only (Per 21 CFR801.109)

System: **Ultrasound System SONIMAGE HS1**

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 (Note3)	P	P	P		P	Note1	Note2
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P	P	P		P	Note1	Note2
	Musculo-skeletal (Superficial)	P	P	P		P	Note1	Note2
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note1	Note2
	Other (Specify)							

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

Note 1: Combined mode BM (B + M), BD (B + Pulse Doppler), BcMc (Color Doppler + M Color Doppler) and BcD (B Color Doppler + Pulse Doppler)

Note 2: Other mode Mc (M Color Mode)

Note 3: Small organ includes thyroid and breast

Prescription Use Only (Per 21 CFR801.109)

System: **Ultrasound System SONIMAGE HS1**

Transducer: **EC9-3**

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	P	P	P		P	Note1	Note2
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	P	P	P		P	Note1	Note2
	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 BM (B + M), BD (B + Pulse Doppler), BcMc (Color Doppler + M Color Doppler) and BcD (B Color Doppler + Pulse Doppler)

Note 2: Other mode Mc (M Color Mode)

Prescription Use Only (Per 21 CFR801.109)

System: **Ultrasound System SONIMAGE HS1**

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 (Note3)	P	P	P		P	Note1	Note2, 4
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P	P	P		P	Note1	Note2, 4
	Musculo-skeletal (Superficial)	P	P	P		P	Note1	Note2, 4
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note1	Note2, 4
	Other (Specify)							

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

Note 1: Combined mode BM (B + M), BD (B + Pulse Doppler), BcMc (Color Doppler + M Color Doppler) and BcD (B Color Doppler + Pulse Doppler)

Note 2: Other mode Mc (M Color Mode)

Note 3: Small organ includes thyroid and breast

Note 4: Other mode Elastography

Prescription Use Only (Per 21 CFR801.109)

System: **Ultrasound System SONIMAGE HS1**

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 (Note3)	P	P	P		P	Note1	Note2
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P	P	P		P	Note1	Note2
	Musculo-skeletal (Superficial)		P	P		P	Note1	Note2
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note1	Note2
	Other (Specify)							

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

Note 1: Combined mode BM (B + M), BD (B + Pulse Doppler), BcMc (Color Doppler + M Color Doppler) and BcD (B Color Doppler + Pulse Doppler)

Note 2: Other mode Mc (M Color Mode)

Note 3: Small organ includes thyroid and breast

Prescription Use Only (Per 21 CFR801.109)

System: **Ultrasound System SONIMAGE HS1**

Transducer: **HL18-4**

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 (Note3)	P	P	P		P	Note1	Note2
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P	P	P		P	Note1	Note2
	Musculo-skeletal (Superficial)	P	P	P		P	Note1	Note2
	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 BM (B + M), BD (B + Pulse Doppler), BcMc (Color Doppler + M Color Doppler) and BcD (B Color Doppler + Pulse Doppler)

Note 2: Other mode Mc (M Color Mode)

Note 3: Small organ includes thyroid and breast

Prescription Use Only (Per 21 CFR801.109)