DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Konica Minolta, Inc.
% Mr. Russell D. Munves
Storch Amini & Munves PC
140 East 45th Street, 25th Floor
NEW YORK NY 10017

November 21, 2014

Re: K142197
Trade/Device Name: Ultrasound System SONIMAGE HS1
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: October 23, 2014
Received: October 27, 2014

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.

This determination of substantial equivalence applies to the following transducers intended for use with the Ultrasound System SONIMAGE HS1, as described in your premarket notification:

Transducer Model Number

L18-4 C5-2

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.
You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K142197

Device Number: Ultrasound System SONIMAGE HS1

Indications for Use:

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 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 (soft tissue), and peripheral vascular.

Type of Use (Select one or both, as applicable)

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

510(k) Summary

Submitter's Name:	KONICA MINOLTA, INC.
Address:	1 Sakura-machi, Hino-shi, 191-8511 Japan
Contact:	Shigeyuki Kojima
Telephone:	+81 42 589 8429
Date:	October 23, 2014
Trade Name:	Ultrasound System SONIMAGE HS1
Model No:	SONIMAGE HS1
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):	K093171 – Viamo SSA-640A, Toshiba America Medical Systems, Inc.

Device Description:

The Ultrasound System SONIMAGE HS1 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 all its modes of B-mode, M-mode, Color Doppler-mode, and PW Doppler-mode.

The optional items are available, such as a Pole Cart with storage basket, a power extension unit, and a foot switch with dual pedals.

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 HS1 and its transducers are designed to comply with the following standards:

AAMI / ANSI ES 60601-1: 2005 and C1:2009 and A2:2010;
IEC 60601-1-6: 2013;
IEC 60601-1-2: 2007;
IEC 60601-2-37: 2007;
IEC 62304: 2006;
ISO 10993-1:2009; ISO 10993-5:2009; ISO 10993-10:2010;
NEMA UD 2-2004; NEMA UD 3-2004;

Intended Use:

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 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 (soft tissue), and peripheral vascular.

This system is contraindicated for an eyeball examination or any other examination that may require the passage of an ultrasound beam through an eyeball. 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 Ultrasound System SONIMAGE HS1 employs the same fundamental scientific technologies as the predicate device (K093171). The comparisons of technological characteristics for both systems are provided as follows;

Intended Use:
The intended use of the system and supporting clinical application are narrowed, but they are still within the scope of predicate device.
The systems are intended to be used with a conventional extracorporeal transducers, which types are Linear and Convex as partially same as those of the predicate device.

Operating Principle and designing:
The system transmits ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and dynamics of the human body. The system is designed in laptop shape to be transportable with battery operation. These operating principle and designing are the same as the predicate device.
The both systems support the same operating modes and display format, the same 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 Pulse Doppler-mode, and the time for Pulse Doppler-mode are comprehensively tested as Bench-tests except quantitative Doppler sensitivity. The both systems do not have a quantitative claims of sensitivity regarding Color Doppler-mode and Pulse Doppler-mode.

Safety:
The system is in conformance with the standards described above, which are same or equivalent standards to those of predicate device. The both systems conform to real time display of thermal and mechanical output indices under Track 3.

Biocompatibility:

The patient contact materials of human body surface are evaluated under ISO 10993 and determined as acceptable for these usage. The 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 HS1 are deemed to be substantially equivalent to the predicate device that have already been cleared for USA distribution with 510(k) premarket notification numbers K093171.