



Food and Drug Administration  
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KONICA MINOLTA, INC.  
% Mr. Russell Munves  
Official Correspondent  
Storch Amini & Munves PC  
140 East 45th Street, 25th Floor  
NEW YORK NY 10017

October 8, 2015

Re: K152577  
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: September 8, 2015  
Received: September 9, 2015

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education 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” (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style with a light grey rectangular highlight behind the text.

Robert Ochs, Ph.D.  
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 (if known)

K152577

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 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), 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							
	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
	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	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
	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)

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
	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: 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	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)	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)

## 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: September 8, 2015

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): K151060 – Ultrasound System SONIMAGE HS1,  
Konica Minolta, Inc.  
K061605 – Nemio XG, SSA-580A,  
Toshiba America Medical Systems, Inc.

Modification Description:

The proposed submission is consisting in several modifications to the Ultrasound System SONIMAGE HS1 referencing as K151060. The modifications are as shown below;

- ✓ Introducing a new transducer and an acoustic standoff
- ✓ Additional options/accessories such as Wireless LAN capability
- ✓ Modifications of system software with regards to the imaging modes (CF(2D)-TDI, PW-TDI, Anatomical-M, and etc.) and the enhancement of measurement and report function

This proposed submission also includes minor design changes.

**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. It is also capable with Anatomical M-mode, CW Doppler-mode and CF/PW-TDI-mode with Sector transducer.

The optional items are available, such as a Pole Cart with storage basket, a power extension 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 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: 2010;  
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), peripheral vascular and cardiac.

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 proposed Ultrasound System SONIMAGE HS1 employs the same fundamental scientific technologies as the primary predicate device (K151060). The imaging hardware is identical to the primary predicate device (K151060). For the functions other than K151060's, the other predicates are referenced such as the Nemio XG SSA-580A system (K061605). The comparisons of technological characteristics for the proposed device and the predicate systems are provided as follows;

##### Intended Use

The Indications for Use Statement is identical to the primary predicate device. The intended use of the system and supporting clinical application operating with a conventional extracorporeal transducers are the same as the predicate devices (K151060 and K061605) that support Linear, Convex and Sector type of ultrasound transducers.

##### 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 devices.

The proposed modifications enhancing the features and the functions are achieved by the system software. No additional hardware is employed to add modes of CF(2D)-TDI, PW-TDI, and Anatomical-M to the primary predicate device (K151060), and those modes operate as same as the other predicates. The wireless connectivity through supporting the OTS USB-WiFi adapter are newly introduced comparing to the predicates, but the complete evaluation as required by the risk analysis has been properly done.

The enhancement of application measurement and report functions by the software modification does not introduce new features other than the traditional items for the conventional ultrasound systems. All referenced literatures are listed in the user manual as same manner as the predicate devices.

The proposed new linear transducer is a conventional extracorporeal transducer, and it employs the same fundamental scientific technologies as the sector transducer of primary predicate device (K151060).

The proposed system and the predicate devices 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, PW/CW Doppler-mode and TDI-mode, and the time for PW/CW Doppler-mode and ECG trace 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, TDI-mode and PW/CW Doppler-mode.

#### Safety

The system is in conformance with the standards described above, which are same standards to those of the primary predicate device (K151060). The both systems conform to real time display of thermal and mechanical output indices under Track 3.

Biocompatibility

The all patient contact materials, including material of an acoustic standoff, of human body surface are evaluated under ISO 10993 and determined as acceptable for these usage. The proposed system and the predicate systems achieve same acceptance level for biocompatibility.

Design Control as per 21CFR 820.30

The proposed device has been verified to meet design specification. The Risk Analysis for the SONIMAGE HS1 has been conducted in accordance with the SOP conforming to ISO14971:2007. The risks associated with all of the identified hazards were reduced to an acceptable level by the risk control measures as shown in Risk Assessment Record. All of the verification activities, as required by the risk analysis, for the proposed system was performed and the results demonstrated that the predetermined acceptance criteria were met.

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 aforementioned predicate devices that have already been cleared for USA distribution with 510(k) premarket notification.