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

August 17, 2016

Hitachi Aloka Medical America, Inc.
% Ms. Angela Van Arsdale
RA/QA Manager
10 Fairfield Blvd.
WALLINGFORD CT 06492-5903

Re: K152126
Trade/Device Name: UST-5550-R; UST-5536-R; L43K
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: August 2, 2016
Received: August 3, 2016

Dear Ms. Van Arsdale:

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152126

Device Name
UST-5550-R
UST-5536-R
L43K

Indications for Use *(Describe)*

The UST-5550-R and UST-5536-R transducer is intended for use with the PROSOUND ALPHA 7 Diagnostic Ultrasound Systems by trained personnel (doctor, sonography, etc.) for the diagnostic ultrasound evaluation during robotic* and non-robotic** intra-operative and laparoscopic procedures.

The L43K transducer is intended for use with the ARIETTA60, ARIETTA70 and NOBLUS Diagnostic Ultrasound Systems by trained personnel (doctor, sonography, etc.) for diagnostic ultrasound evaluation during robotic* and non-robotic** intra-operative and laparoscopic procedures.

This device is not indicated for Ophthalmic applications.

*For robotic use, these devices can only be used with the da Vinci™ Surgical System and da Vinci™ 8 mm ProGrasp Forceps.
**For non-robotic use, these devices can only be used with the Covidien SILS™ Clinch

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND ALPHA 7 Ultrasound systems
Transducer: UST-5550-R
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Specify)	Other** (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Neurosurgery)							
	Laparoscopic	P	P	P		P	P	P
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify)							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac – Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA in K122537 E = added under Appendix 1 - Specifications
Combination of each operating mode includes:

*1 Combination of each operating mode- B/M, B/PWD, M/CD, B/CD/PWD, B/CD

**2 Includes: Mflow, B/Bflow, Power flow.

Additional Comments:

Subscript "a": Includes imaging of organs and structures exposed during surgery (Excluding neurosurgery procedures).

Prescription Use Only (Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND ALPHA 7 Ultrasound systems
Transducer: UST-5536-R
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Specify)	Other** (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Neurosurgery)							
	Laparoscopic	P	P	P		P	P	P
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify)							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac – Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA in K122537 E = added under Appendix 1 - Specifications
Combination of each operating mode includes:

*1 Combination of each operating mode- B/M, B/PWD, M/CD, B/CD/PWD, B/CD

**2 Includes: Mflow, B/Bflow, Power flow.

Additional Comments:

Subscript "a": Includes imaging of organs and structures exposed during surgery (Excluding neurosurgery procedures).

Prescription Use Only (Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 60, ARIETTA 70 and NOBLUS Ultrasound systems
Transducer: L43K
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Specify)	Other** (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Neurosurgery)							
	Laparoscopic	P	P	P		P	P	P
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify)							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac – Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA in K140443, K134016 & K142368 E = added under Appendix 1 - Specifications
Combination of each operating mode includes:

*1 Combination of each operating mode - B/M, B/PWD, M/CD, B/CD/PWD, B/CD

**2 Includes: Mflow, B/Bflow, Power flow.

Additional Comments:

Subscript "a": Includes imaging of organs and structures exposed during surgery (Excluding neurosurgery procedures).

Prescription Use Only (Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Prescription Use Only (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

Hitachi Aloka Medical America, Inc.
10 FAIRFIELD BOULEVARD, WALLINGFORD, CT 06492
U.S.A.

HITACHI, LTD.
2-16-1, Higashi-Ueno, Taito-ku
TOKYO, 110-0015 JAPAN

510(k) Summary of Safety and Effectiveness in accordance with 21 CFR Part 807, Subpart E, Section 807.92.

21 CFR 807.92, Subsection a

1. Submitter's Information:

Address: Hitachi Aloka Medical America, Inc.
10 Fairfield Boulevard
Wallingford, CT 06492-5903
Contact: Angela Van Arsdale
RA/QA Manager
Telephone: (203) 269-5088 Ext: 346
Fax Number: (203) 269-6075
Date Prepared: July 28, 2015

2. Device / Common / Classification Name / Classification / Product Code:

Device Proprietary Name(s): **L43K**
Manufacturer: *Hitachi, Ltd. Healthcare Tokyo Works*
3-7-19 Imai,
Ome-Shi, Tokyo 198-8577 Japan
Common Name: Diagnostic Ultrasound Transducer
Classification: Class II
Product Code: 90-ITX 892.1570 Diagnostic Ultrasonic Transducer

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Device Proprietary Name(s): **UST-5550-R;**
UST-5536-R;
Manufactured in the U.S.A. by: *MD MedTec, LLC.*
14 Inverness Drive E, Suite F140
Englewood, Colorado 80112 U.S.A.

Manufactured for: *Hitachi, Ltd.*
2-16-1, Higashi-Ueno, Taito-ku
TOKYO, 110-0015 JAPAN

Common Name: Diagnostic Ultrasound Transducer
Classification: Class II
Product Code: 90-ITX 892.1570 Diagnostic Ultrasonic Transducer

3. Legally Marketed Predicate Device(s):

UST-5536-7.5 Intraoperative Ultrasound Transducer [K111227];
EUP-O54J Intraoperative Ultrasound Transducer [K142368]

4. Device Description:

Linear Array transducer

5. Indication for Use:

The UST-5550-R and UST-5536-R transducer is intended for use with the PROSOUND ALPHA 7 Diagnostic Ultrasound Systems by trained personnel (doctor, sonography, etc.) for the diagnostic ultrasound evaluation during robotic* and non-robotic** intra-operative and laparoscopic procedures.

The L43K transducer is intended for use with the ARIETTA60, ARIETTA70 and NOBLUS Diagnostic Ultrasound Systems by trained personnel (doctor, sonography, etc.) for diagnostic ultrasound evaluation during robotic* and non-robotic** intra-operative and laparoscopic procedures.

This device is not indicated for Ophthalmic applications.

*For robotic use, these devices can only be used with the da Vinci™ Surgical System and da Vinci™ 8 mm ProGrasp Forceps.
**For non-robotic use, these devices can only be used with the Covidien SILS™ Clinch

21 CFR 807.92, Subsection a – *Continued*

6. Comparison to predicate device:

The UST-5550-R, UST-5536-R and L43K Intraoperative linear transducers are technically comparable and substantially equivalent to the currently marketed UST-5536-7.5 and EUP-O54J. The difference between the subject devices (UST-5550-R, UST-5536-R & L43K) and predicate (UST-5536-7.5) is the material change to Titanium and dimensional/design changes to the probe head to include a linear ridge. The UST-5550-R and UST-5536-R have the same array dimension, number of elements and element spacing as the predicate UST-5536-7.5.

The subject devices UST-5550-R and UST-5536-R are manufactured in the U.S.A. by SOMA Manufacturing, LLC in accordance to specifications and components provided by the manufacturer: Hitachi Aloka Medical, Ltd. located in Tokyo, Japan.

The subject device L43K contains the same array dimension, number of element and element spacing as the predicate EUP-O54J Intraoperative linear transducer with the same probe head design and material as the UST-5550-R & UST-5536-R.

The L43K is manufactured in its entirety by Hitachi, Ltd., Japan.

The subject and predicate transducers are compatible with track 3 diagnostic ultrasound systems and incorporate the same fundamental and scientific technologies. The only difference between the subject and predicate devices is a material change; along with minor dimensional and design modifications to probe head at the distal end of the subject devices. The material has been changed to Titanium and the shape of the scanning head is modified to add a small linear ridge to allow surgical graspers or robotic arm graspers to hold and control the scanning head during intraoperative or laparoscopic procedures. Neither the changes to the scanning head (dimensional and material) or the use of either surgical graspers or robotic arm graspers to manipulate the device change the intended use of the device.

The following compares the subject and predicate devices:

Subject devices:	**Predicate devices:**
Reusable device	Reusable device
New material: Titanium	All materials previously cleared by FDA
Intraoperative linear array	Intraoperative linear array
Modes of operation: B, M, PWD, CD, PowerFlow and Combination of each operating mode	Modes of operation: B, M, PWD, CD, PowerFlow and Combination of each operating mode

21 CFR Part 807.92, Section b

<table>
<tr><td>1. Non-clinical Testing:</td><td>No new hazards were identified with the modification to the scanning head. The bend and flexibility durability testing demonstrates that the material change to Titanium of the transducer head shell and the “T’ attaching mechanism design to all the option grasping the transducer head by either a da Vinci 8mm ProGrasp grasping mechanism or Covidien SILS manual grasper instruments for intra-operative or laparoscopic procedure scanning does not add any additional risk nor effect image quality.

The following outlines the testing:
<table>
<tr><th>Test</th><th>Acceptance Criteria</th><th>Result</th></tr>
<tr><td>Grasp and Release Test with da Vinci 8 mm ProGrasp robotic arm</td><td>Grasp and release with UST-5550-R /L43K the 8mm ProGrasp robotic arm starting straight, 180° and straight and releasing 100/500 times. The L43K must complete the testing without loss of imaging performance or broken and/or loose components.</td><td>Pass – after completing 100 and 500 grasp and release movements there is no signs of physical damage and no changes in imaging performance.</td></tr>
<tr><td>Bend and Flexibility Test with da Vinci 8 mm ProGrasp robotic arm</td><td>Bend and Release with UST-5550-R /L43K with da Vinci S and Prograsp 8mm Forceps. All Robotic Ultrasound Probe samples must complete 500/1000 random articulations in a north, south, east and west direction without loss of imaging performance, broken and/or loose components.</td><td>Pass – after completing 500 and 1000 random articulations in a north, south, east and west direction there were no broken and/or loose components and no loss of imaging performance.</td></tr>
</table></td></tr>
<tr><td>2. Clinical testing:</td><td>None required</td></tr>
<tr><td>3. Conclusion:</td><td>The UST-5550-R, UST-5536-R and L43K Transducers is substantially equivalent in safety and effectiveness to the predicate device(s);

▪ The subject and predicate device(s) are both indicated for inter-operative diagnostic ultrasound imaging.
▪ The subject and predicate device(s) have the same gray scale and doppler capabilities.
▪ The subject and predicate device(s) have the same essential technology for imaging, doppler functions and signal processing.
▪ The subject and predicate device(s) have acoustic level below the Track 3 FDA limits.
▪ The subject and predicate device(s) are manufactured in accordance to FDA 21 CFR 820 Quality System Regulations.
▪ The subject and predicate device(s) are designed and manufactured to the same electrical and physical safety standards.
▪ The subject and predicate device(s) are manufactured with materials that have been tested in accordance to ISO 10993-1; all biocompatibility testing has been conducted in accordance to each component material characterization, type of body contact, and duration contact risk profile.
▪ The subject and predicate device(s) are supplied non-sterile with instructions for cleaning, disinfection and sterilization in the transducer manuals.</td></tr>
</table>

END OF SUMMARY