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

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

December 3, 2014

Re: K142618
Trade/Device Name: UST-5310 or UST-5310-TIP / UST-5311 or UST-5311-TIP
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: September 12, 2014
Received: September 16, 2014

Dear Ms. Arsdale:

This letter corrects our substantially equivalent letter of October 16, 2014.

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,

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

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 on last page.

510(k) Number *(if known)*

K142618

Device Name

UST-5310 or UST-5310-TIP / UST-5311 or UST-5311-TIP

Indications for Use *(Describe)*

The Hitachi Aloka Medical, Ltd UST-5310 or UST-5310-TIP / UST-5311 or UST-5311-TIP transducers are intended for use with the PROSOUND ALPHA 6, PROSOUND ALPHA 7 and ARIETTA70 Diagnostic Ultrasound systems by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation during intra-operative and Intra-operative (neurosurgery) procedures.

This device is not indicated for Ophthalmic applications.

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

[x] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

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

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND ALPHA 6, PROSOUND ALPHA 7 and ARIETTA 70
Transducer: UST-5310 or UST-5310-TIP
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)*	P	P	P		P	P	P
	Intra-operative (Neurosurgery)	P	P	P		P	P	P
	Laparoscopic**							
	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 via K140854
Combination of each operating mode includes:

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

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

Intra-operative (Specify)* - (liver, pancreas, gall bladder..)

(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)_____

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND ALPHA 6, PROSOUND ALPHA 7 and ARIETTA 70
Transducer: UST-5311 or UST-5311-TIP
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)*	P	P	P		P	P	P
	Intra-operative (Neurosurgery)	P	P	P		P	P	P
	Laparoscopic**							
	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 via K140854
Combination of each operating mode includes:
*1 Combination of each operating mode- B/M, B/PWD, M/CD, B/CD/PWD
**2 Includes: Mflow, B/Bflow, Power flow.

Intra-operative (Specify)* - (liver, pancreas, gall bladder..)

(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)

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

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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

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

Manufacturer:
Hitachi Aloka Medical, Ltd.
6-22-1 Mure, Mitaka-Shi, 181-8622
Tokyo, Japan

Date Prepared: September 12, 2014

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

Device Proprietary Name – UST-5310 or UST-5310-TIP / UST-5311 or UST-5311-TIP
Common name - Diagnostic Ultrasound Transducer
Classification name - Diagnostic Ultrasonic Transducer
Classification: Class II
Product Code: 90-ITX 892.1570 Diagnostic Ultrasonic Transducer

3. Legally Marketed Predicate Device(s):

UST-5310 or UST-5310-TIP / UST-5311 or UST-5311-TIP Intraoperative Ultrasound Transducer for use with PROSOUND ALPHA 6 [K140854].

4. Device Description:

Linear Array transducer

5. Indication for Use:

The Hitachi Aloka Medical, Ltd UST-5310 or UST-5310-TIP / UST-5311 or UST-5311-TIP transducers are intended for use with the PROSOUND ALPHA 6, PROSOUND ALPHA 7 and ARIETTA70 Diagnostic Ultrasound systems by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation during intra- operative and Intra-operative (neurosurgery) procedures.

This device is not indicated for Ophthalmic applications.

6. Comparison to predicate device:

The Hitachi Aloka Medical, Ltd. UST-5310 or UST-5310-TIP / UST-5311 or UST-5311-TIP Intraoperative transducers cleared via K140854 for use with the PROSOUND ALPHA 6 have not undergone any modifications, therefore there are no changes to either of the transducers. The two transducers are being added for use with the PROSOUND ALPHA7 and ARIETTA70 Diagnostic Ultrasound systems. The subject systems: PROSOUND ALPHA7 & ARIETTA70 Diagnostic Ultrasound system and predicate system: PROSOUND ALPHA 6 (K093488 / K140854) are track 3 systems that incorporate the same fundamental and scientific technologies. There are no changes to the PROSOUND ALPHA7 and ARIETTA70 Diagnostic Ultrasound scanners with the exception of connection and recognition of the UST-5310 and UST-5311 transducers.

21 CFR Part 807.92, Section b

1. Non-clinical Testing

No new hazards were identified with the addition of the UST-5310 and UST-5311 transducers to the PROSOUND ALPHA7 & ARIETTA70. The subject systems and the transducers have been evaluated for acoustic output, biocompatibility, electromagnetic compatibility, as well as electrical and mechanical safety, and have been found to conform to applicable medical device safety standards.

2. Clinical testing:

None required

3. Conclusions:

The Hitachi Aloka Medical, Ltd. Sterile Transducer is substantially equivalent in safety and effectiveness to the predicate device;

- The subject and predicate device(s) are both indicated for 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 predicate transducers [UST-5310 & UST-5311] are sterile single use disposable devices.

END OF SUMMARY