



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Qingdao Hisense Medical Equipment Co., Ltd.
% Mr. Mark Job
Responsible Third Party Official
1394 25th Street, NW
BUFFALO MN 55313

July 17, 2015

Re: K151709
Trade/Device Name: Hi-Light Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: June 23, 2015
Received: June 24, 2015

Dear Mr. Job:

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 blue ink that reads "Michael D. O'Hara". The signature is written over a large, semi-transparent watermark of the FDA logo.

For

Robert Ochs, Ph.D.
Acting 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)

K151709

Device Name

Hi-Light Diagnostic Ultrasound System

Indications for Use (Describe)

This diagnostic ultrasound system (Hi-Light) and its transducers are intended for use in clinical examinations to evaluate differences in the echogenicity of soft tissue of small parts in adult patients (thyroid, breast, and testicles) and for superficial muscular skeletal diagnosis.

The system is for prescription use only by a trained sonographer under the direction of a qualified physician or directly by a qualified physician.

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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Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (specify)							
	Intra-operative (neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (specify) Breast, Thyroid, Testes	N						
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-cardiac)							
	Musculo-skeletal (conventional)							
	Musculo-skeletal (superficial)	N						
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral vessel							
	Other (specify)							

System: Hi-Light Diagnostic Ultrasound System N = new indication; P= previously cleared by FDA

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 (specify) Breast, Thyroid, Testes	N						
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-cardiac)							
	Musculo-skeletal (conventional)							
	Musculo-skeletal (superficial)	N						
	Intravascular							
Other (specify)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral vessel							
	Other (specify)							

Transducer: LA06 transducer for use with Hi-Light N = new indication; P= previously cleared by FDA

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: _____

Submitter:

Qingdao Hisense Medical Equipment Co., Ltd.
No. 169 Songling Road, Laoshan District
Qingdao City, Shandong Province, China
Tel: 86- 532-55753841
Fax: 86(0)532-55753841

Official Correspondent:

Wangwei
Project Manager of Qingdao Hisense Medical Equipment Co., Ltd.
Tel : 86(0) 532-55753841 Fax: 86(0) 532-55753841
Email:wangwei@hisense.com

US Agent:

Guy Scott
WinProbe Corporation
11770 US Hwy 1 Suite 405E
Palm Beach Gardens, FL 33408
Tel: (561)626 4405
Email:gscott@winprobe.com

Date Prepared:

February 19, 2015

Device Name and Classification:

Common/Usual Name:
Diagnostic Ultrasound System
Proprietary Name:
Hi-Light Diagnostic Ultrasound System

Classification Name:

21 CFR 892.1560 Ultrasonic, Pulsed Echo, Imaging
21 CFR 892.1570 Transducer, Ultrasonic, Diagnostic

Product Codes: IYO, ITX

Regulatory Class: Class II

Predicate Device:

Siemens Acuson S2000 Ultrasound System, K081148

Device description:

The Hi-Light is a portable Diagnostic Ultrasound System, which applies the latest technologies to produce optimal images. The system facilitates a workflow from image acquisition through to archival in a standard DICOM interface to the clinics PACs system. Various image parameter adjustments, a 15 inch high resolution display and custom probes are configured to provide clear and stable images. The modes of operation include B mode.

Intended Use:

This diagnostic ultrasound system (Hi-Light) and its transducers are intended for use in clinical examinations to evaluate differences in the echogenicity of soft tissue of small parts in adult patients ,(thyroid, breast, and testicles) and for superficial muscular skeletal diagnosis.

The system is for prescription use only by a trained sonographer under the direction of a qualified physician or directly by a qualified physician.

Clinical Test: Clinical testing not required

Non-clinical Test:

Testing according to the following safety standards are conducted on the subject device:

1. IEC 60601-1 Safety Requirements for Medical Equipment, 2012
2. IEC 60601-1-2 EMC Requirements for Medical Equipment, 2007
3. IEC 60601-2-37 Diagnostic Ultrasound Safety Standards, 2007
4. Acoustic output testing as per the FDA guidance “Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers”, dated September 9, 2008
5. ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing,2003, ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity,1999, ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity,2002, ISO 10993-11, Biological Evaluation of Medical Devices – Part 11: Tests for systemic toxicity,2006

Comparison to the predicate device:

The Hi-Light diagnostic ultrasound system uses the same fundamental scientific technologies as the predicate device (Siemens Acuson S2000, K081148). Table 1 compares the Hi-Light to the predicate device with respect to indications for use, intended use, and principles of operation for the determination of substantial equivalence.

Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd.	Siemens
Trade Name	Hi-Light	Acuson S2000
510(k) Number	-	K081148
Product Code	IYO, ITX	IYN, IYO, ITX
Regulation Number	892.1560 892.1570	892.1550 892.1560 892.1570
Regulation Name	Ultrasonic pulsed echo	Ultrasonic pulsed Doppler imaging

	imaging	system
Indications for Use	<p>This diagnostic ultrasound system (Hi-Light) and its transducers are intended for use in clinical examinations to evaluate differences in the echogenicity of soft tissue of small parts in adult patients ,(thyroid, breast, and testicles) and for superficial muscular skeletal diagnosis.</p> <p>The system is for prescription use only by a trained sonographer under the direction of a qualified physician or directly by a qualified physician.</p>	<p>The Modified S2000, the S2000 ABVS Ultrasound system, is intended for the following applications: General Radiology, Abdominal, Fetal, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Pediatric, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications. The system supports the transducers listed in the Ultrasound Indications for Use tables, including the 14L5BV for B-mode imaging of a patient’s breast using an optional automatic scanning function. The device is not intended to be used as a replacement for screening mammography. The system also provides for the measurement of anatomical structures and analysis as provided in the original S2000 Ultrasound System, which provides information that is used by medical health care professionals for clinical diagnosis purposes.</p>
Significant Differences	<p>The main difference is the size</p> <p>Dimensions: 364 mm (W) x 63.5 mm(H) x 375mm (D)</p> <p>Weight: 5 kg</p>	<p>Dimensions: 623 mm (W) x 1300 mm (H) x 1103 mm (D)</p> <p>Weight: 166 kg</p>

Table 1. Predicate Device Comparison

Intended Use:

The intended use and clinical applications of the Hi-Light system are narrowed, but still in the scope of the predicate device. Both systems are intended to be used with a conventional extracorporeal transducer. The type of transducer specified for use with the Hi-Light system is linear which is also used with the predicate system. A comparison of the transducers is provided in Table 2:

	LA06 (Hi-Light)	14L5 (Acuson S2000 K081148)
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Type	Linear	Linear
Frequency Bandwidth	5 – 12 MHz	5 – 14 MHz
Applications	<ul style="list-style-type: none"> • Breast • Testes • Thyroid • Musculoskeletal 	<ul style="list-style-type: none"> • Breast • Testes • Thyroid • Musculoskeletal • Peripheral Vessel
Number of Elements	128	128
Modes of Operation	B	B, C, D, M
Array Footprint	38.1 mm	39 mm

Table 2. Probe Comparison

Operating Principle and Design:

Both the Hi-Light and the predicate system transmit ultrasonic energy into patients then perform post processing of received echoes to generate on-screen displays of anatomic structures of the human body. Both systems are designed with an LCD display screen and hand-held transducers. Both systems support the same operating mode (B) and the same measurement functions for anatomic structures. The operation characteristics (installation and use, mode of operation) and the power supply are the same in both systems.

Non-clinical Test and Safety:

The Hi-Light system is in conformance with the standards described above which are the same or equivalent to those of the predicate device.

Biocompatibility:

The patient contact materials of human body surface are evaluated under ISO 10993 and determined acceptable for the specified usage of the system. Both systems have the same acceptance level for biocompatibility.

Conclusion:

Clinical studies are not required to support substantial equivalence for these conventional ultrasound systems. In addition, as discussed in the above technological comparison, the technological characteristics of the Hi-Light system are substantially equivalent to the referenced predicate device that has been previously cleared for USA distribution.

Substantially Equivalent Determination:

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same operational characteristics as the previously cleared predicate device, or the device has the same intended use and different operational characteristics in which substantial equivalency can be demonstrated in the device in comparison to the predicate device. In addition, the new device does not raise new questions regarding its safety and effectiveness as compared to the predicate device. It is shown in this 510(k) submission that the difference between the Hi-Light and the predicate device does not raise any questions regarding its safety and effectiveness. The Hi-Light, as designed and produced, is determined to be substantially

equivalent to the predicate device.