June 8, 2022

Qingdao Hisense Medical Equipment Co., Ltd
% Yalan Wu
Regulatory Affair Manager
No. 399 Songling Road, Laoshan District
Qingdao, Shandong 266100
P. R. CHINA

Re: K213862
Trade/Device Name: HD60 Series Ultrasound Diagnostic System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: April 29, 2022
Received: May 10, 2022

Dear Yalan Wu:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Michael D. O'Hara, Ph.D.
Deputy Director
DHT 8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT 8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213862

Device Name
HD60 Series Ultrasound diagnostic System

Indications for Use *(Describe)*

The HD60 Series Ultrasound Diagnostic System is a general-purpose ultrasound system. It is intended for use by, or under the direction of a qualified and trained physician for ultrasound imaging, measurement, display and analysis of the human body and fluid. The device is intended for use in a hospital environment.

The systems support the following clinical applications:
The HD60 series Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ, neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac (adult, pediatric), peripheral vessel, and urology exams.

Modes of operation include: 3D/4D Imaging mode, B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Combined modes: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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."

510(k) Summary

(K213862)

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date Prepared:	Nov 26, 2021
Manufacturer:	Qingdao Hisense Medical Equipment Co., Ltd No. 399 Songling Road, Laoshan District 266100, Qingdao, Shandong, P. R. China
Contact Person:	Yalan Wu Regulatory Affair Mananger Qingdao Hisense Medical Equipment Co., Ltd Tel: +86-532-55752797 wuyalan@Hisense.com

Identification of the Device:

Proprietary/Trade Name:	HD60 Series Ultrasound Diagnostic System
Classification Name:	Ultrasound Diagnostic System
Regulatory Number:	21 CFR 892.1550, 21 CFR 892.1560, 21 CFR 892.1570
Product Code:	IYN,IYO,ITX
Device Class:	Class II
Review Panel:	Radiology

Identification of the Legally Marketed Predicate Device:

Trade Name:	DC-80/DC-80PRO/DC-80EXP/DC-80S/DC-85 /DC-86/DC-86S/DC-89/DC-TV/DC-TQ
Classification Name:	Ultrasound Diagnostic System
Regulatory Number:	21 CFR 892.1550, 1560, 1570
Product Code:	IYN, ITX, IYO, LLZ
Device Class:	Class II
Review Panel:	Radiology
Submitter/510(k) Holder:	Shenzhen Mindray Bio-medical Electronics Co., LTD.
Clearance:	K192152 (cleared December 13, 2019)

Reference Device:

Trade Name:	DC-70/DC-70T/DC-70 Pro/DC-70 Exp
Classification Name:	Ultrasound Diagnostic System
Regulatory Number:	21 CFR 892.1550, 1560, 1570
Product Code:	IYN, ITX, IYO, LLZ
Device Class:	Class II
Review Panel:	Radiology
Submitter/510(k) Holder:	Shenzhen Mindray Bio-medical Electronics Co., LTD.
Clearance:	K150204 (cleared April 10, 2015)

Device Description:

The HD60 Series consists of a mobile console with a height-adjustable control panel, color LCD touch panel, LCD display monitor and optional image storage and printing device. It includes a variety of electronic array transducers operating in linear, curved, sector/phase array, and real time 3D transducer.
HD60 series is a Track 3 diagnostic ultrasound system. The system includes electronics for transmit and receive of ultrasound data, ultrasound signal processing, software computing, hardware for image storage, hard copy printing, and network access to the facility through LAN.

Indications for Use:

The HD60 Series Ultrasound Diagnostic System is a general-purpose ultrasound system. It is intended for use by, or under the direction of a qualified and trained physician for ultrasound imaging, measurement, display and analysis of the human body and fluid. The device is intended for use in a hospital environment.

The systems support the following clinical applications:

The HD60 series Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ, neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac (adult, pediatric), peripheral vessel, and urology exams.

Modes of operation include: 3D/4D Imaging mode, B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Combined modes: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

Comparison with Predicate Device:

The HD60 series Ultrasound Diagnostic System and its predicate device, the DC-80/DC-80PRO/DC-80EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/ DC-TQ Ultrasound Diagnostic System (K192152), have the same intended use, and similar physical characteristics.

Description	**Subject Device** Hisense HD60 Ultrasound Diagnostic System	**Predicate Device** Mindray DC80 Ultrasound Diagnostic System **(K192152)**
Indications for use	It is intended for use in abdominal, fetal, pediatric, Small Organ, neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), cardiac(adult, pediatric), peripheral vessel, and urology exams.	It is intended for use in abdominal, fetal, intra-operative(abdominal, thoracic, and vascular), pediatric, Small Organ(breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), cardiac(adult, pediatric), trans-esoph.(Cardiac), peripheral vessel, and urology exams.
User	Qualified and trained physician	Qualified and trained physician
Environment	Hospital environment	Hospital environment
Design	Autocorrelation for color processing and FFT for pulse Doppler processing. Supporting Linear, Curve, Phase array and Volume probes.	Autocorrelation for color processing and FFT for pulse Doppler processing. Supporting Linear, Curve, Phase array and Volume probes.
Patient Contact Materials	Material meet ISO 10993-1 and FDA guidance	Material meet ISO 10993-1 and FDA guidance
Mode of operation	3D/4D Imaging mode, B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Combined	3D/4D Imaging mode, B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Combined

Description	Subject Device Hisense HD60 Ultrasound Diagnostic System	Predicate Device Mindray DC80 Ultrasound Diagnostic System **(K192152)**
	modes: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.	modes: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
Functions	➢ Spatial compound imaging ➢ Frequency compound imaging ➢ One-Click Optimization ➢ Speckle reduction imaging (SRI) ➢ PDI (power Doppler imaging), DPDI (directional power Doppler imaging), and TDI (tissue Doppler imaging) ➢ Angle deflection of linear array probes ➢ High-pulse repetition frequency ➢ Puncture guidance and puncture enhancement, with real-time double-screen comparison ➢ Tissue-specific imaging ➢ Extended imaging ➢ TVI (Tissue Doppler imaging, TDI) ➢ Curve Anatomical M Mode ➢ Strain rate imaging ➢ Elastography (Elasticity imaging)	➢ iBeam ➢ Frequency compound imaging ➢ iTouch (Auto Image Optimization) ➢ iClear image enhancement ➢ PDI (power Doppler imaging), DPDI (directional power Doppler imaging), and TDI (tissue Doppler imaging) ➢ Deflection scanning by linear array probes ➢ HPRF ➢ Puncture guidance ➢ Tissue-specific imaging ➢ ExFOV (Extended FOV) ➢ Tissue Doppler imaging, TDI (TVI) ➢ Free Xros CM ➢ Strain rate analysis ➢ Elastography (Elasticity imaging)

Description	Subject Device Hisense HD60 Ultrasound Diagnostic System	Predicate Device Mindray DC80 Ultrasound Diagnostic System **(K192152)**
	➢ High-resolution blood flow ➢ Image comparison (dynamic and static images) ➢ DICOM ➢ **Teaching System** ➢ ECG	➢ High-resolution blood flow ➢ Image comparison (dynamic and static images) ➢ DICOM ➢ ECG
Measurements	**Basic measurement:** Distance, Area, Circumference Volume, Velocity, Time **Measurement kits:** Routine measurement Abdominal measurement kit Gynecological measurement kit Obstetric measurement kit Urological measurement kit Small part measurement kit Vascular measurement kit Cardiac measurement kit Pediatric measurement kit Emergency measurement kit Automatic measurement of intima-media thickness (IMT) Automatic spectrum envelope measurement	**Basic measurement:** Distance, Area, Circumference Volume, Velocity, Time **Measurement kits:** Routine measurement Abdominal measurement kit Gynecological measurement kit Obstetric measurement kit Urological measurement kit Small part measurement kit Vascular measurement kit Cardiac measurement kit Pediatric measurement kit Emergency measurement kit Automatic measurement of intima-media thickness (IMT) Automatic spectrum envelope measurement
Transducer Types	Convex array Phased array Linear array Micro convex array Volume	Convex array Phased array Linear array Micro convex array Volume
Acoustic Output within FDA guidelines	Track 3; Ispta.3 ≤ 720 mW/cm2 MI ≤ 1.9	Track 3; Ispta.3 ≤ 720 mW/cm2 MI ≤ 1.9

Description	Subject Device Hisense HD60 Ultrasound Diagnostic System	Predicate Device Mindray DC80 Ultrasound Diagnostic System **(K192152)**
	TI ≤ 6.0	TI ≤ 6.0
general safety and effectiveness information	ANSI/AAMI ES60601-1 IEC60601-2-37 IEC60601-1-2 ISO 10993-1	ANSI/AAMI ES60601-1 IEC60601-2-37 IEC60601-1-2 ISO 10993-1
Labeling	Conforms to 21 CFR Part 801	Conforms to 21 CFR Part 801
Accessories	foot switch ECG cable and Leadwire B/W Printer	Foot switch ECG B/W Printer

Technology:
The HD60 Series employs the same fundamental scientific technology as its predicated device.

Determination of substantial equivalence:
The Proposed HD60 Series system are substantially equivalent to the predicate the DC-80/DC-80PRO/DC-80EXP/DC-80S/DC-85/DC-86/DC-86S/ DC-89/DC-TV/DC-TQ Ultrasound Diagnostic System (K192152) with regards to intended use, indication for use, image capabilities, technological characteristics, image mode, and safety effectiveness.
The following is an overview of the differences between the proposed HD60 Series and its predicate device.
Comparison Analysis
Note 1:
Indication for use:
The Indication for use of subject device does not support intra-operative (abdominal, thoracic, and vascular) and trans-esoph.(Cardiac). As the subject device does not support intra-operative and trans-esoph probe. It is less than Predicate device. They can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

Note 2:
Patient Contact Materials:
The Patient Contact Materials of the probes is equivalent to the predicated device, both the subject and predicated device probe material meet ISO 10993-1 and FDA guidance requirement. They can be considered

Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

Note 3:
Functions:
Teaching System is new functions compare with predicate device. Other functions are same, just name description is minor different for some functions. The teaching feature is same as “iScanhelper” of Diagnostic Ultrasound System model DC-70/DC-70T/DC-70 Pro/DC-70 Exp manufactured by Mindray (K150204 cleared on April 10, 2015). By providing the referential information, such as, displays the standard ultrasonic image, anatomical sketch, scanning approach image and scanning tips, the system helps the doctors to operate the scanning by teaching system. Furthermore, it is a good platform for the self-learning and training of ultrasound scanning technique for doctors. The system also plays a role in the assistant software system in fulfilling training and education. It is verified and meet the requirement. It can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.
The teaching system is intended for off line training and not live guidance during real time imaging. The teaching system is for teaching only and should not be used for diagnostic purposes.

Summary of Non-clinical test:
HD60 Series were evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and have been found to comply with applicable medical device safety standard, The HD60 Series complies with voluntary standards:

1. AAMI/ANSI ES60601-1: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance, 2005/A2:2012
2. IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Disturbance – Requirements and tests, 2014
3. IEC 60601-2-37 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, Ed2.1, 2015
4. ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, 2018
5. ISO 10993-5 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
6. ISO 10993-10 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization

7. IEC62359, Ultrasonics-Field characterization- Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2017.
8. ISO 14971 Medical Devices - Applications of Risk Management to Medical Devices, 2019
9. NEMA PS3.1-3.20, Digital Imaging and Communications in Medicine (DICOM) Set.(radiology), 2016.
10. IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
11. IEC 62366 Consolidated Version Medical Devices - Application of Usability Engineering to Medical Devices
12. IEC 62304 Medical Device Software - Software Life Cycle Processes

The following quality assurance measures are applied to the development of the system:

Risk Management
Requirement review and Design reviews
Integration testing (system verification)
Performance testing (Verification)
Safety testing (Verification)

Transducer material and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, did not require clinical studies to support substantial equivalence.

Conclusion:

Hisense Considers the HD60 Series Ultrasound Diagnostic System to be as safe, as effective, and performance is substantially equivalent to the predicate device.