February 21, 2024

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

Re: K233439
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: January 23, 2024
Received: January 23, 2024

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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product;

and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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,

Marjan Nabili -S for

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: 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)*
K233439

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.

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510(k) Summary

K233439

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

Date Prepared:	Sep 26, 2023
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 Manager 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
Regulation Name:	Ultrasonic Pulsed Doppler Imaging 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

Primary Predicate Device:

Proprietary/Trade Name:	HD60 Series Ultrasound Diagnostic System
Classification Name:	Ultrasound Diagnostic System
Regulation Name:	Ultrasonic Pulsed Doppler Imaging 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
Submitter/510(k) Holder:	Qingdao Hisense Medical Equipment Co., Ltd

Clearance:	K213862 (cleared June 8, 2022)

Reference Device (1):

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
Regulation Name:	Ultrasonic Pulsed Doppler Imaging System
Regulatory Number:	21 CFR 892.1550, 1560, 1570
Product Code:	IYN, IYO, ITX, 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 (2):

Trade Name:	Resona R9, Resona R9 Exp, Resona R9 Pro, Resona R9S, Nuewa R9, Nuewa R9, Exp, Nuewa R9 Pro, Nuewa R9S, Resona 7, Resona 7CV, Resona 7EXP, Resona 7S, Resona 7OB, Resona 7PRO, Imagyn 7, Resona Y, Resona R9W, Resona R7W, Nuewa R9W, Nuewa R7W
Classification Name:	Ultrasound Diagnostic System
Regulation Name:	Ultrasonic Pulsed Doppler Imaging System
Regulatory Number:	21 CFR 892.1550, 1560, 1570
Product Code:	IYN, IYO, ITX
Device Class:	Class II
Review Panel:	Radiology
Submitter/510(k) Holder:	Shenzhen Mindray Bio-medical Electronics Co., LTD.
Clearance:	K222928 (cleared Feb 7, 2023)

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 or Wireless with WIFI adapter module.

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 previous generation of HD60 series Ultrasound Diagnostic System (K213862), have the same intended use, and similar physical characteristics.

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 HD60 Series Ultrasound Diagnostic System (K213862) with regards to intended use, indication for use, image capabilities, technological characteristics, image mode, and safety effectiveness.
The changes base on previous HD60 series Ultrasound Diagnostic System as below:
Note 1: Patient Contact Materials.
The Patient Contact Materials of the new added 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 2: Functions.
(1) New added functions which is same as reference device
CAMM (Curved Anatomy M-Mode), HiNeedle, Biopsy, Echo Enhance, TDI QA, C-Elasto, Contrast (Contrast Imaging), Auto Track, R Flow (Ribbon Flow), Dual Live, HiStep, DVR, Gesture Settings, Voice Comment, MFI (Micro Flow Imaging): are new functions compare with predicate device. These features are exactly same as the Diagnostic Ultrasound System model DC-80 (K192152 cleared December 13, 2019), and Resona 7 (K222928 (cleared Feb 7, 2023) manufactured by Mindray. The SE is not affected.
(2) New added functions which is not support on predicated/reference device
There are three functions of 3D PW (3DSpectral), SCV(Spectral Color Velocity), and MSV(Multi-sample volume) which are not support on predicated/reference device. The performance of them all meets the requirements. These new function has no impact on safety or effectiveness.
The three new added functions of the HD60 series are features that are used to characterize blood flow measurements.

Note 3: Measurements.
New added measurement of Pelvic Floor Measurement kit, Obstetric Auto Measurement, Auto NT Measurement, Cardiac Auto measurement which are same as reference, the Diagnostic Ultrasound System model DC-80 manufactured by Mindray (K192152 cleared December 13, 2019). The SE is not affected.

Note 4: WIFI.
Adding WIFI module, and the device support wireless function to connect LAN. The device with WIFI module was verified on safety/EMC, software and cybersecurity, The SE is not affected.

Note 5: Other change.
(1) Product console models change:
Total 93 console models after adding/deleting console models, the difference between the models are software functions. The model list as below:
HD60、HD60S、HD60G、HD60Q、HD60T、HD60E、HD60EXP、HD60Pro; HD58EXP、HD58Pro、HD58Plus、HD58; HD59EXP、HD59Pro、HD59Plus、HD59; HD62EXP、HD62Pro、HD62Plus、HD62; HD55、HD55S、HD55G、HD55Q、HD55T、HD55E、HD55Plus; HD50、

HD50S、HD50G、HD50Q、HD50T、HD50E、HD50Plus; HD48、HD48S、HD48G、HD48Q、HD48T、HD48E、HD48Plus; HD45、HD45S、HD45G、HD45Q、HD45T、HD45E、HD45Plus; HD42、HD42S、HD42G、HD42Q、HD42T、HD42E、HD42Plus; HD40、HD40S、HD40G、HD40Q、HD40T、HD40E、HD40Plus; HD35、HD35S、HD35G、 HD35Q、HD35T、HD35E、HD35Plus; HD30、HD30S、HD30G、HD30Q、HD30T、HD30E、HD30EXP、HD30Pro; HD25、HD25S、HD25G、HD25Q、HD25T、HD25E、HD25EXP、HD25Pro; HD20、HD20S、HD20G、HD20Q、HD20T、HD20E、HD20EXP、HD20Pro;

(2) Adding new probes models

Total support 30 probe models after adding/deleting probes: L15-5EL, L12-3EB, L15-5EB, L15-5E, L9-3E, L14-6E, L9-3A, L12-4L, L12-3E, SC7-1E, SC8-2E, C5-2A, C5-2L, C5-1E, P5-1A, P8-2EJ, P4-1EL, P4-1EB, P4-1L, P4-1E, E9-3E, E9-4E, E9-4EL, E9-4L, E9-4B, DC6-2A, DC7-2A, DE10-3E, MC11-3A, ECL11-4E.

The new added probes have same indication for use, and equivalent material.

(3) Optimize software function

DICOM preset (such as image print preset, enquire or store preset) optimize.

Above modifications can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

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. ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
2. IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
3. IEC/TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
4. IEC 60601-2-37 Edition 2.1 2015 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

5. IEC62359, Ultrasonics-Field characterization- Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2017.
6. ISO10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
7. ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
8. ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
9. ISO10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation
10. ISO14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices
11. NEMAPS 3.1 - 3.20 2022d Digital Imaging and Communications in Medicine (DICOM) Set.
12. IEC60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
13. IEC62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION Medical devices - Part 1: Application of usability engineering to medical devices
14. IEC62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes
15. ISTA3B 2017 Packaged-Products for Less-Than-Truckload (LTL) Shipment

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.