



May 16, 2024

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

Re: K233841

Trade/Device Name: HD80 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 16, 2024
Received: April 16, 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 (the 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 available 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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Indications for Use

Submission Number (if known)

K233841

Device Name

HD80 Series Ultrasound Diagnostic System

Indications for Use (Describe)

The HD80 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 HD80 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.

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510(k) Summary**K233841**

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

Date Prepared: Nov 30, 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: HD80 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:

Trade Name: Resona R9, Resona R9 Exp, Resona R9 Pro, Resona R9S, Nueva R9, Nueva R9, Exp, Nueva R9 Pro, Nueva R9S, Resona 7, Resona 7CV, Resona 7EXP, Resona 7S, Resona 7OB, Resona 7PRO, Imagyn 7, Resona Y, Resona R9W, Resona R7W, Nueva R9W, Nueva 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 HD80 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. HD80 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 HD80 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 HD80 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 HD80 series Ultrasound Diagnostic System and its predicate device, the HD60 series Ultrasound Diagnostic System (K213862), have the same intended use, and similar physical characteristics.

Description	Subject Device Hisense HD80 Ultrasound Diagnostic System	Predicate Device Hisense HD60 Ultrasound Diagnostic System (K213862)
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, pediatric, Small Organ, neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), cardiac(adult, pediatric), 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	3D/4D Imaging mode, B, M, PW Doppler, CW Doppler, Color Doppler, Color M

Description	Subject Device Hisense HD80 Ultrasound Diagnostic System	Predicate Device Hisense HD60 Ultrasound Diagnostic System (K213862)
	Doppler, Power Doppler, Harmonic Imaging, Combined modes: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.	Doppler, Power Doppler, Harmonic Imaging, Combined 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 (C-Elasto) ➤ High-resolution blood flow	➤ 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 (C-Elasto) ➤ High-resolution blood flow

Description	Subject Device Hisense HD80 Ultrasound Diagnostic System	Predicate Device Hisense HD60 Ultrasound Diagnostic System (K213862)
	➤ Image comparison (dynamic and static images) ➤ DICOM ➤ Teaching System ➤ ECG ➤ Contrast imaging ➤ Automated workflow (Hi-Step) ➤ Lithotripsy guide (Middle line) ➤ Voice comment ➤ Ribbon flow imaging (R Flow) ➤ 3D spectral Doppler imaging (3D PW) ➤ Spectral color velocity (SCV) imaging	➤ Image comparison (dynamic and static images) ➤ DICOM ➤ Teaching System ➤ ECG ➤ Contrast imaging ➤ Automated workflow (Hi-Step) ➤ Lithotripsy guide (Middle line) ➤ Voice comment
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	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

Description	Subject Device Hisense HD80 Ultrasound Diagnostic System	Predicate Device Hisense HD60 Ultrasound Diagnostic System (K213862)
	Emergency measurement kit Automatic measurement of intima-media thickness (IMT) Automatic spectrum envelope measurement Thorax Measurement	Emergency measurement kit Automatic measurement of intima-media thickness (IMT) Automatic spectrum envelope measurement Thorax 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; $Ispta.3 \leq 720$ mW/cm^2 $MI \leq 1.9$ $TI \leq 6.0$	Track 3; $Ispta.3 \leq 720$ mW/cm^2 $MI \leq 1.9$ $TI \leq 6.0$
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 WIFI module Battery	foot switch ECG cable and Leadwire B/W Printer

Technology:

The HD80 Series employs the same fundamental scientific technology as its predicated device.

Determination of substantial equivalence:

The Proposed HD80 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 following is an overview of the differences between the proposed HD80 Series and its predicate device.

Comparison Analysis

Note 1: Patient Contact Materials.

The Patient Contact Materials of 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 function is equivalent as reference device

Ribbon flow imaging (R Flow) is a new function compare with predicate device. The feature is equivalent as Resona R9 Ultrasonic pulsed doppler imaging system (K222928) manufactured by Mindray. The SE is not affected.

(2) New added functions which is not support on predicated/reference device
There are two functions of 3D PW (3DSpectral) and SCV(Spectral Color Velocity) which are not support on predicated/reference device. The performance of them meets the requirements. These new functions have no impact on safety or effectiveness.

The two new added functions of the HD80 series are features that are used to characterize blood flow measurements.

Note 3: WIFI and battery

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.

The Li-Battery was added and the system with battery was verified on safety/EMC and performance, The SE is not affected.

Summary of Non-clinical test:

HD80 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 HD80 Series complies with voluntary standards:

1. ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 &

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- 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
 16. IEC 62133-2:2017+AMD1:2021 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

Summary of Clinical Tests:

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

Conclusion:

Hisense Considers the HD80 Series Ultrasound Diagnostic System to be as safe, as effective, and performance is substantially equivalent to the predicate device.