Shenzhen Mindray Bio-medical Electronics Co., Ltd. November 9, 2020
℅ Jiang Haosen
Engineer of Technical Regulation
Mindray Building, Keji 12th Road South,
Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057
P.R. CHINA

Re: K201990
Trade/Device Name: DC-30/DC-32/DC-28/DC-26/DC-25/DC-20/DC-30 Exp/DC-32 Exp Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: October 9, 2020
Received: October 13, 2020

Dear Jiang Haosen:

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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*

K201990

Device Name
DC-30/DC-32/DC-28/DC-26/DC-25/DC-20/DC-30 Exp/DC-32 Exp Diagnostic Ultrasound System

Indications for Use *(Describe)*

DC-30/DC-32/DC-28/DC-26/DC-25/DC-20/DC-30 Exp/DC-32 Exp Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ (breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac (adult, pediatric), peripheral vessel, and urology exams.

This device is a general purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid, which is intended to be used in a hospital or medical clinic.

Modes of operation include: B, M, PW Doppler, Color Doppler, Amplitude Doppler, Tissue Harmonic Imaging, Smart 3D, 4D (Real-time 3D), iScape, Biopsy Guidance, Elastography, Contrast imaging (Contrast agent for Liver) and Combined mode: B+M, PW+B, Color+B, Power+B, PW+Color+B, Power+PW+B.

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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K201990

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. Submitter:

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Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: November 2, 2020

2. Device Name:

DC-30/DC-32/DC-28/DC-26/DC-25/DC-20/DC-30 Exp/DC-32 Exp Diagnostic Ultrasound System

Classification

Regulatory Class: II

Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (IYN)

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (ITX)

3. Device Description:

DC-30/DC-32/DC-28/DC-26/DC-25/DC-20/DC-30 Exp/DC-32 Exp Diagnostic Ultrasound System is a general purpose, mobile, software controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound images in B-mode, M-mode, PW-mode, CW mode, Color-mode, Power/Dirpower mode, THI mode, 3D/4D mode, iScape mode, Biopsy Guidance, Elastography, Contrast imaging (Contrast agent for Liver) or the combined mode (i.e. B/M-Mode).

This system is a Track 3 device that employs an array of probes that include linear array, convex array and phased array.

4. Indications for Use:

DC-30/DC-32/DC-28/DC-26/DC-25/DC-20/DC-30 Exp/DC-32 Exp Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ (breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac (adult, pediatric), peripheral vessel, and urology exams.

This device is a general purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid, which is intended to be used in a hospital or medical clinic.

Modes of operation include: B, M, PW Doppler, Color Doppler, Amplitude Doppler, Tissue Harmonic Imaging, Smart 3D, 4D (Real-time 3D), iScape, Biopsy Guidance, Elastography, Contrast imaging (Contrast agent for Liver) and Combined mode: B+M, PW+B, Color+B, Power+B, PW+Color+B, Power+PW+B.

5. Summary of Modifications

New Added Models:

DC-20, DC-30 Exp, DC-32 Exp

New Added Transducers:

C6-2P, V10-4BP, 7L4BP, 6LE7P;

New Added Needle-Guided Bracket:
NGB-009, NGB-022;

Main Added Features:

1. iNeedle
2. Smart Face
3. Smart NT;
4. Smart OB;
5. iLive;
6. Add Elastography to 7L4P

Other changes:

1. Add transducer element check
2. Change the monitor to a 21.5' monitor
3. Unregister transducer CB10-4P

6. Comparison with Predicate Devices:

DC-30/DC-32/DC-28/DC-26/DC-25/DC-20/DC-30 Exp/DC-32 Exp Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Control Number
1. Primary predicate device	Mindray	DC-30	K173369
2. Reference device	Mindray	DC-40	K183377
3. Reference device	Mindray	Z60	K200411

DC-30/DC-32/DC-28/DC-26/DC-25/DC-20/DC-30 Exp/DC-32 Exp Diagnostic Ultrasound System employs the same technology as the predicate devices. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations. The subject device also has the same intended uses and basic operating modes as the predicate

devices.

- Subject device DC-30/DC-32/DC-28/DC-26/DC-25/DC-20/DC-30 Exp/DC-32 Exp has the similar intended uses with the predicated device DC-30 (K173369) .

Items	Subject Device DC-30/DC-32/DC-28/DC-26/DC-25/DC-20/DC-30 Exp/DC-32 Exp	Predicate device DC-30 series (K173369)	S/D
Indications for Use	Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ (breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac (adult, pediatric), peripheral vessel, and urology exams. This device is a general purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid, which is intended to be used in a hospital or medical clinic. Modes of operation include: B, M, PW Doppler, Color Doppler, Amplitude Doppler, Tissue Harmonic Imaging, Smart 3D, 4D (Real-time 3D), iScape, Biopsy Guidance, Elastography, Contrast imaging (Contrast agent for Liver) and Combined mode: B+M, PW+B, Color+B, Power+B, PW+Color+B, Power+PW+B.	Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ (breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac (adult, pediatric), peripheral vessel and urology exams.	S

- The added probes and Needle-guided brackets of DC-30/DC-32/DC-28/DC-26/DC-25/DC-20/DC-30 Exp/DC-32 Exp are similar to the predicate device Z60 (K200411) and DC-40 (K183377).

Subject Device DC-30	DC-40 (Predicate device K183377)	Z60 (Predicate device K200411)
C6-2P	C6-2	/
7L4BP	7L4A	/
V10-4BP	/	V10-4BP
6LEP7	/	6LE7P
NGB-009	NGB-009	/
NGB-022	NGB-022	/

- The added features of DC-30/DC-32/DC-28/DC-26/DC-25/DC-20/DC-30 Exp/DC-32 Exp has the same performance and functions with the predicated device Z60 (K200411) and DC-40 (K183377).

Subject Device DC-30	DC-40 (Predicate device K183377)	Z60 (Predicate device K200411)
Smart Face	Smart Face	/
Smart NT	Smart NT	/
Smart OB	Smart OB	/
iLive	iLive	/
Elastography to 7L4P	Elastography	/
iNeedle	/	iNeedle
Transducer element check	/	Transducer element check

- The acoustic power levels of DC-30/DC-32/DC-28/DC-26/DC-25/DC-20/DC-30 Exp/DC-32 Exp are below the limits of FDA, which is the same as the predicated device DC-30 (K173369).

Items	DC-30/DC-32/DC-28/DC-26/DC-25/DC-20/DC-30 Exp/DC-32 Exp	DC-30 series (K173369)	S/D
Track 3	√	√	S

- DC-30/DC-32/DC-28/DC-26/DC-25/DC-20/DC-30 Exp/DC-32 Exp is designed in compliance with the FDA recognized electrical and physical safety standards, which are the same as the predicated device DC-30 (K173369).

	Items	DC-30/DC-32/DC-28/DC-26/DC-25/DC-20/DC-30 Exp/DC-32 Exp	DC-30 series (K173369)	S/D
1	AAMI/ANSI 60601-1	√	√	S
2	IEC 60601-1-2	√	√	S
3	IEC60601-2-37	√	√	S
4	IEC 62304	√	√	S
5	IEC 62366-1	√	√	S
6	ISO 14971	√	√	S
7	IEC 60601-1-6	√	√	S
8	NEMA UD 2	√	√	S
9	ISO 10993-1	√	√	S

7. Non-clinical Tests:

DC-30/DC-32/DC-28/DC-26/DC-25/DC-20/DC-30 Exp/DC-32 Exp Diagnostic Ultrasound System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical safety standards.

Non-clinical tests relied on in this premarket notification submission for a determination of substantial equivalence include testing showing compliance with the following standards:

- AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance (iec 60601-1:2005, mod).
- IEC 60601-1-2 Edition 4.0 2014-02, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard:

electromagnetic compatibility - requirements and tests.

- 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.
- IEC 62304 Edition 1.1 2015-06, medical device software - software life cycle processes.
- ISO 14971 Second edition 2007-03-01, medical devices - application of risk management to medical devices.
- NEMA UD 2-2004 (R2009), acoustic output measurement standard for diagnostic ultrasound equipment revision 3.
- AAMI / ANSI / ISO 10993-1:2009/(R)2013, biological evaluation of medical devices - part 1: evaluation and testing within a risk management process.
- IEC 62366-1 Edition 1.0 2015-02 Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]
- IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

8. Clinical Tests:

Not Applicable.

9. Summary

Based on the performance data as documented in the study, the DC-30 Diagnostic Ultrasound system was found to have a safety and effectiveness profile that is similar to the predicate device.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the DC-30/DC-32/DC-28/DC-26/DC-25/DC-20/DC-30 Exp/DC-32 Exp Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.