Shenzhen Mindray Bio-medical Electronics Co., Ltd.
% Zhang Wei
Engineer of Technical Regulation
Mindray Building, Keji 12th Road South
Hi-tech Industrial Park
Nanshan, Shenzhen 518057
P.R. CHINA

August 21, 2020

Re: K201693
Trade/Device Name: DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/ DC-80A Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 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, LLZ
Dated: May 20, 2020
Received: June 30, 2020

Dear Zhang Wei:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201693

Device Name
DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 Diagnostic Ultrasound System

Indications for Use *(Describe)*

DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, Intra-operative(abdominal, thoracic, and vascular), pediatric, small organ(breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), adult and pediatric cardiac, Trans-esoph. (Cardiac), 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, PWD, CWD, Color Doppler, Amplitude Doppler, Tissue Harmonic Imaging, Smart 3D, 4D, iScape, TDI, Color M, Biopsy Guidance, Elastography, Contrast imaging (Contrast agent for Liver), Contrast imaging (Contrast agent for LVO), STE, STQ, Ultrasound Fusion Imaging, GYN/Pelvic 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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010-1

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.

The assigned 510(k) number: K201693

1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD
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Contact Person:
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Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: May 20, 2020

2. Device Name:

DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 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)

21 CFR 892.2050 Picture Archiving and Communications System(LLZ)

3. Predicate Device

Predicate Device	Manufacturer	Device Name	Devie Class	Product Code	510(k) Control Number
1. Primary predicate device	Mindray	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S /DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System	II	IYN, IYO, ITX and LLZ	K192152
2. Reference device	Mindray	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S /DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System	II	IYN, IYO, ITX	K173471
3. Reference device	Mindray	Resona 7/ Resona 7CV/ Resona 7EXP/ Resona 7S/ Resona 7OB Diagnostic Ultrasound System	II	IYN, IYO, ITX	K171233

Regulation name and code

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)

21 CFR 892.2050 Picture Archiving and Communications System(LLZ)

4. Device Description:

DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A Exp/ DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 Diagnostic Ultrasound System is a general purpose, mobile, software controlled, ultrasound diagnostic system.

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

The new added transducers C5-1E，SC5-1E，C6-2GE，C7-3E，L14-6WE，L16-4HE，P10-4E，6LB7E，CB10-4E，V11-3E，V11-3BE，DE10-3WE，D7-2E，P7-3TE，CW5s were cleared in FDA (K192152) and the CW2s were cleared in FDA (K173471);

L13-3WE is equivalent with transducer L14-5WE, which was cleared in FDA (K192152).

The needle-guided brackets in this submission were cleared in FDA (K192152) and (K200001).

The materials used in the new transducers (except for L13-3WE) and needle-guided brackets were the same as in the predicate device. And the L13-3WE transducer was testing for biocompatibility.

All the transducers and needle-guided brackets were provided non-sterile to the end user. And all the disinfection/sterilization methods for the new transducers and needle guide brackets were provided to the end user and the users are notified that disinfection /sterilizaiton are necessary in the Operation Manual.

5. Intended Use:

The DC-80A /DC-80A Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82/DC-88/DC-90/ DC-95/DC-88S/DC-90S/DC-95S/DC-90Q Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, Intra-operative(abdominal, thoracic, and vascular), pediatric, small organ(breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), adult and pediatric cardiac, Trans-esoph. (Cardiac), 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, PWD, CWD, Color Doppler, Amplitude Doppler, Tissue Harmonic Imaging, Smart 3D, 4D, iScape, TDI, Color M, Biopsy Guidance, Elastography, Contrast imaging (Contrast agent for Liver), Contrast imaging (Contrast agent for LVO), STE, STQ, Ultrasound Fusion Imaging, GYN/Pelvic and Combined mode:B+M, PW+B, Color+B, Power+B, PW+Color+B, Power+PW+B.

6. Summary of Modifications

New Added Transducers:

C5-1E，SC5-1E，C6-2GE，C7-3E，L14-6WE，L16-4HE，L13-3WE，P10-4E，6LB7E，CB10-4E ，V11-3E，V11-3BE，DE10-3WE，D7-2E，P7-3TE，CW5s，CW2s;

New Added Needle-Guided Bracket:

NGB-004、NGB-009、NGB-019、NGB-021、NGB-024、NGB-031、NGB-054;

Main Added Features:

1. Ultrasound Fusion Imaging to C5-1E, SP5-1E, SC5-1E, L14-5WE, SC6-1E;
2. Smart Pelvic to C5-1E, V11-3HE, D7-2E, DE11-3E, SC5-1E, C6-2GE, V11-3E, V11-3BE, SC6-1E, SD8-1E, DE10-3WE, C7-3E;
3. STE/STQ to L13-3WE, SC5-1E, C5-1E
4. Strain Elastography to L14-6WE、L13-3WE、V11-3E、V11-3BE
5. Add the Fetal to the Clinical Application of L9-3E;
6. Add the contrast imaging(Contrast imaging for Liver) function to SC5-1E、C5-1E、C6-2GE、C7-3E
7. RIMT;
8. Smart Planes FH;
9. Glazing Flow;
10. Fusion RESP;

The other New changes:

1. STIC function to D7-2E;
2. Add Transducer Element Check;
3. OS Upgrade from win7 to win10;
4. Add Macfee anti-virus software.

7. Comparison with Predicate Devices:

DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A Exp/ DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 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-80	K192152
2. Reference device	Mindray	DC-80	K173471

3. Reference device	Mindray	Resona 7	K171233

DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A Exp/ DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 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-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A Exp/ DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 has the same probes and indication for use and modes of operation with the predicated device DC-80 (K192152) , Reference device DC-80 (K173471)& Resona 7 (K171233)

Subject Device DC-90	DC-80(predicate device) (K192152)	DC-80(Reference device) (K173471)	Resona 7(Reference device) (K171233)
C5-1E	C5-1E	/	/
SC5-1E	SC5-1E	/	/
C6-2GE	C6-2GE	/	/
C7-3E	C7-3E	/	/
L14-6WE	L14-6WE	/	/
L16-4HE	L16-4HE	/	/
L13-3WE	L14-5WE	/	/
P10-4E	P10-4E	/	/
6LB7E	6LB7E	/	/
CB10-4E	CB10-4E	/	/
V11-3E	V11-3E	/	/
V11-3BE	V11-3BE	/	/
DE10-3WE	DE10-3WE	/	/
D7-2E	D7-2E	/	/
P7-3TE	P7-3TE	/	/

CW5s	CW5s	/	/
CW2s	/	CW2s	/
L9-3E	/	/	L9-3E

DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 has the same performance and functions with the predicated device DC-80 (K192152) .

Subject Device DC-90	**Predicate device DC-80 (K192152)**
Ultrasound Fusion Imaging	Ultrasound Fusion Imaging
Smart Pelvic	Smart Pelvic
STE/STQ	STE/STQ
Elastography	Elastography
Contrast imaging	Contrast imaging
Smart Planes FH	Smart Planes FH
Fusion RESP	Fusion RESP
Glazing Flow	Glazing Flow
Subject Device DC-90	**Reference device Resona 7(K171233)**
RIMT	RIMT

- The materials of probes and Needle-guided brackets of DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 are the same to the predicate device DC-80 (K192152).
- The acoustic power levels of DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 are below the limits of FDA, which is the same as the predicated device DC-80 (K192152).
- DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 is designed in compliance with the FDA recognized electrical and physical safety standards, which are the same as the predicated device DC-80 (K192152).

8. Non-clinical Tests:

DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A Exp/

DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 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

9. Clinical Tests:

Not Applicable.

10. Summary

Based on the performance data as documented in the study, the DC-90 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-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/ DC-88S/DC-80A/DC-80A Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.