September 29, 2022

Shenzhen Mindray Bio-medical Electronics Co., Ltd
℅ Zhang Wei
Engineer of Technical Regulation
Keji 12th Road South, Hi-tech Industrial Park
Shenzhen, Guangdong 518057
CHINA

Re: K221496
Trade/Device Name: Consona N6, Consona N6 Pro, Consona N6 Super, Consona AR, Consona N6S, Consona AE, Consona AT, Consona N6 Exp, Consona N6 Elite, Consona N6T 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: August 5, 2022
Received: August 25, 2022

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,

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)*

K221496

Device Name

Consona N6, Consona N6 Pro, Consona N6 Super, Consona AR, Consona N6S, Consona AE, Consona AT, Consona N6 Exp, Consona N6 Elite, Consona N6T Diagnostic Ultrasound System

Indications for Use *(Describe)*

Consona N6, Consona N6 Pro, Consona N6 Super, Consona AR, Consona N6S, Consona AE, Consona AT, Consona N6 Exp, Consona N6 Elite, Consona N6T Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates.
It is intended for use in fetal, abdominal, Intra-operative, pediatric, small organ(breast, thyroid, testes), neonatal cephalic,adult cephalic,trans-rectal, trans-vaginal, musculo-skeletal(conventional), musculo- skeletal(superficial), Thoracic/Pleural, cardiac adult, cardiac pediatric, Trans-esoph., peripheral vessel and urology exams.

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

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.

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.

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(c).

The assigned 510(k) number: **K221496**

1. Submitter

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Date Prepared: September 19 2022

2. Device Name

Consona N6, Consona N6 Pro, Consona N6 Super, Consona AR, Consona N6S, Consona AE, Consona AT, Consona N6 Exp, Consona N6 Elite, Consona N6T 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. Predicate devices

Consona N6 series Diagnostic Ultrasound System is substantially equivalent in its technologies and functionality to MX7 Diagnostic Ultrasound System (predicate devices) that are already cleared by FDA, and they are listed below. MX7 is the main predicate devices.

Device	Manufacturer	Model	Device Class	Product Code	510K Number
1. Main predicate device	Mindray	MX7	II	IYN, IYO, ITX	K212900
2. Reference device	Mindray	Resona I9	II	IYN, IYO, ITX	K210699
3. Reference device	Mindray	DC-90	II	IYN, IYO, ITX, LLZ	K201693
4. Reference device	Mindray	DC-40	II	IYN, IYO, ITX	K183377
5. Reference device	Mindray	Resona R9	II	IYN, IYO, ITX	K202785
6. Reference device	Mindray	DC-7	II	IYN, IYO, ITX,	K103583

4. Device Description:

Consona N6, Consona N6 Pro, Consona N6 Super, Consona AR, Consona N6S, Consona AE, Consona AT, Consona N6 Exp, Consona N6 Elite, Consona N6T Diagnostic Ultrasound System is a general purpose, mobile, software controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound images in Modes of operation include : B, M, PWD, CWD, Color Doppler, Amplitude Doppler, Combined mode(B+M, PW+B, Color+B, Power+B, PW+Color+B, Power+PW+B), Tissue Harmonic Imaging, Smart 3D, 4D(Real-time 3D), iScape View, TDI, Color M, Strain Elastography, Contrast imaging (Contrast agent for LVO), Contrast imaging (Contrast agent for Liver).

Subject device can also measure anatomical structures and offer analysis packages to provide information based on which the competent health care professionals can make the diagnosis.

5. Intended Use:

Consona N6, Consona N6 Pro, Consona N6 Super, Consona AR, Consona N6S, Consona AE, Consona AT, Consona N6 Exp, Consona N6 Elite, Consona N6T Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, Intra-operative, pediatric, small organ(breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional), musculo- skeletal(superficial), Thoracic/Pleural, cardiac adult, cardiac pediatric, Trans-esoph., peripheral vessel and urology exams.

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

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.

6. Comparison with Predicate Devices:

Subject device Consona N6, Consona N6 Pro, Consona N6 Super, Consona AR, Consona N6S, Consona AE, Consona AT, Consona N6 Exp, Consona N6 Elite, Consona N6T Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices mentioned in *3. Predicate* Devices with regards to intended use, imaging modes, features and functions and technological characteristics.

- All systems transmit ultrasonic energy into patients, 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, as well as calculations.
- Indications for use

Items	Subject Device Consona N6 series	Predicate device MX7 (K212900)
Indications for use	Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, Intra-operative, pediatric, small organ(breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional), musculo-skeletal(superficial), Thoracic/Pleural, cardiac adult, cardiac pediatric, Trans-esoph., peripheral vessel and urology exams.	Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in ophthalmic, fetal, abdominal, pediatric, small organ (breast, thyroid, testes), neonatal cephalic, adult cephalic, transrectal, trans-vaginal, musculo-skeletal(conventional), musculo-skeletal(superficial), thoracic/pleural, cardiac adult, cardiac pediatric, peripheral vessel and urology, intra-operative(abdominal, thoracic, and vascular) , trans-esoph(Cardiac) exams

- The patient contact materials of the transducers and needle-guided brackets of subject device are the same to the predicate devices or tested under ISO 10993-1.
- The acoustic power levels of subject device are below the limits of FDA, which are the same as the predicated device MX7 (K212900).
- The subject device is designed in compliance with the FDA recognized electrical and physical safety standards, which are the same as the predicated device MX7 (K212900).
- The subject device has the same features and functions as the predicated devices.
- **A technological comparison between your device and predicate devices**

Items	Subject Device Consona N6 series	Predicate device MX7 (K212900)	Predicate device Resona I9 (K210699)	Predicate device Resona R9 (K202785)
Transducers				

Convex probe (C5-1, SC5-1N, C6-2, 3C5A, C11-3, C6-1, DE11-3, SD8-1, D7-2, D6-2B)	√	√	√	√
Linear probe (L13-3N, L13-3,7L4B, L9-3, L14-3W,7LT4, L20-5s, L16-4Hs, ELC10-4,6LE7)	√	√	√	√
Phased array probe (P4-2, SP5-1N, P8-2, P10-4)	√	√	√	√
Intracavitary probe (V11-3HB, V11-3H, V11-3, V11-3B, V10-4, V10-4B,6CV1)	√	√	√	√
Pen probe (CW2s, CW5s)	√	√	√	√
TEE probe (P7-3Ts, P8-3Ts, P8-2Ts)	√	√	√	√
Mode				
B	√	√	√	√
M	√	√	√	√
PWD	√	√	√	√
CWD	√	√	√	√
Color Doppler	√	√	√	√
Amplitude Doppler	√	√	√	√
Combined （specify）	√	√	√	√
Features				
CW	√	√	√	√
4D	√	/	√	√
iScape View	√	√	√	√
Free Xros M	√	√	√	√
Free Xros CM	√	√	√	√
Tissue Doppler Imaging	√	√	√	√

TDI QA	√	√	√	√
Contrast imaging	√	√	√	√
Contrast Imaging QA	√	√	√	√
LVO	√	√	√	√
Strain Elastography	√	√	√	√
Stress Echo	√	√	√	√
Tissue Tracking QA	√	√	√	√
Smart 3D	√	√	√	√
iPage+	√	/	√	√
SCV+	√	/	√	√
iLive	√	/	√	√
Color 3D	√	/	√	√
Niche	√	/	√	√
Smart Volume	√	/	√	√
Smart Face	√	/	√	√
Glazing Flow	√	/	√	√
iNeedle	√	√	√	√
Abdomen/General Package	√	√	√	√
Obstetrics Package	√	√	√	√
Gynecology Package	√	√	√	√
Cardiology Package	√	√	√	√
Small Parts Package	√	√	√	√
Urology Package	√	√	√	√
Vascular Package	√	√	√	√
Pediatrics Package	√	√	√	√
Nerve Package	√	√	√	√
Emergency&Critical Package	√	√	√	√
Smart Pelvic	√	/	√	√
Smart OB	√	√	√	√
Smart NT	√	√	√	√
IVF	√	/	√	√
IMT	√	/	√	√
RIMT	√	√	√	√

AutoEF	√	√	√	√
R-VQS	√	√	√	√
Smart Hip	√	/	√	√
Smart HRI	√	/	√	√
Smart Bladder	√	√	/	/
Smart Trace	√	/	√	√
CPP	√	√	√	√
Smart B-line	√	√	√	/
V-Mapping	√	/	√	/
DICOM Basic	√	√	√	√
DICOM Worklist	√	√	√	√
DICOM MPPS	√	√	√	√
DICOM Query/Retrieve	√	√	√	√
DICOM OB/GYN SR	√	√	√	√
DICOM Vascular SR	√	√	√	√
DICOM Cardiac SR	√	√	√	√
DICOM Breast SR	√	√	√	√
DICOM Abdomen SR	√	√	√	√
DICOM Small Parts SR	√	/	√	√
iWorks	√	√	√	√
DVR Module	√	√	√	√
iVocal	√	√	√	/
New Features				
Smart Calc	√	/	/	/
ClamAV	√	/	/	/
Hardware				
Text printer	√	√	√	√
Video printer	√	√	√	√
Barcode reader	√	√	√	√
Footswitch	√	√	√	√
ECG	√	√	√	√
Battery	√	√	√	√

For the differences compared to the predicate devices:

- The subject device **introduces new options,** which in the below table that either the improvements or enhancement based on the cleared functions to facilitate user, no intended uses are added and passed the related tests, no clinical risks introduced.

Subject Device	Function explanation	predicate device
Smart Calc	Semi-automatically recognizes the contour of the target area and measures the diameter, area and circumference of the target area. The user needs to identify the target area first. When the measures results are not satisfactory, the user can use the trackball to manually edit the contour.	Resona R9 (K202785)
ClamAV	This is an anti-virus software	/

7. Non-clinical Tests:

Consona N6, Consona N6 Pro, Consona N6 Super, Consona AR, Consona N6S, Consona AE, Consona AT, Consona N6 Exp, Consona N6 Elite, Consona N6T 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 designed to conform with applicable medical safety standards. This device has been tested and evaluated under the following standards:

- NEMA UD 2-2004 (R2009), acoustic output measurement standard for diagnostic ultrasound equipment revision 3.
- 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 disturbances - Requirements and tests
- 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.
- 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.
- ISO 14971 Second edition 2007-03-01, medical devices - application of risk management to medical devices.
- ISO 10993-1 Fifth edition 2018-08, biological evaluation of medical devices -

part 1: evaluation and testing within a risk management process.

- IEC 62304 Edition 1.1 2015-06, medical device software - software life cycle processes.
- IEC 62366-1 Edition 1.0 2015-02 Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)].

These non-clinical tests relied on in this premarket notification submission can support the determination of substantial equivalence of the subject device.

8. Clinical Studies

Not applicable. The subject of this submission, Consona N6, Consona N6 Pro, Consona N6 Super, Consona AR, Consona N6S, Consona AE, Consona AT, Consona N6 Exp, Consona N6 Elite, Consona N6T Diagnostic Ultrasound System, does not require clinical studies to support substantial equivalence.

9. Summary

Based on the performance data as documented in the study, the Consona N6, Consona N6 Pro, Consona N6 Super, Consona AR, Consona N6S, Consona AE, Consona AT, Consona N6 Exp, Consona N6 Elite, Consona N6T Diagnostic Ultrasound System was found to have a safety and effectiveness profile that is similar to the predicate device.

10.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 Consona N6, Consona N6 Pro, Consona N6 Super, Consona AR, Consona N6S, Consona AE, Consona AT, Consona N6 Exp, Consona N6 Elite, Consona N6T Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to primary predicate device.