May 3, 2024

Contec Medical Systems Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd
Rm. 912, Building #15, XiYueHui, No.5, YiHe North Rd.
FangShan District, Beijing 102401
CHINA

Re: K232895
Trade/Device Name: B-Ultrasound Diagnostic System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: March 26, 2024
Received: March 26, 2024

Dear Ray Wang:

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,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
DHT8C: Division of Radiological Imaging
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Office of Product Evaluation and Quality
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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)*
K232895

Device Name
B-Ultrasound Diagnostic System

Indications for Use *(Describe)*
B-Ultrasound Diagnostic System in a general-purpose, digital ultrasound diagnostic system for abdomen, gynecology, obstetric, urology, and small-parts application.
The system is intended to use for the following type of studies: fetal organ, abdominal, pediatric, small organs (Thyroid, Galactophore, Testis), neonatal cephalic, peripheral vascular, and musculo-skeletal (both conventional and superficial).
The device is intended to adult, pregnant woman, pediatric and neonate.
The system is a prescription device intended to be used by or on the order of a physician or similar qualified health care professional.
This device is not intended for home use.
Modes of operation include B, M, PWD(PW), B+M, 2B, 4B.
Please refer to the acoustic output declaration for each transducer in 510(K) Summary.

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

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

The assigned 510(k) Number: K232895

1. Date of Preparation: 05/01/2024

2. Sponsor

Contec Medical Systems Co., Ltd
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3. Submission Correspondent

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4. Proposed Device Identification

Trade Name: B-Ultrasound Diagnostic System
Common Name: System, Imaging, Pulsed Echo, Ultrasonic; Transducer, Ultrasonic, Diagnostic
Model(s): CMS600P2PLUS
Regulatory Information:
Classification Name: System, Imaging, Pulsed Echo, Ultrasonic; Transducer, Ultrasonic,

Diagnostic
Classification: II
Product Code: IYO; ITX
Regulation Number: 21 CFR 892.1560; 21 CFR 892.1570
Regulation Name: Ultrasonic pulsed echo imaging system
Review Panel: Radiology

Indication For Use Statement:
B-Ultrasound Diagnostic System in a general-purpose, digital ultrasound diagnostic system for abdomen, gynecology, obstetric, urology, and small-parts application.
The system is intended to use for the following type of studies: fetal organ, abdominal, pediatric, small organs (Thyroid, Galactophore, Testis), neonatal cephalic, peripheral vascular, and musculo-skeletal (both conventional and superficial). The device is intended to adult, pregnant woman, pediatric and neonate.
The system is a prescription device intended to be used by or on the order of a physician or similar qualified health care professional.
This device is not intended for home use.
Modes of operation include B, M, PWD(PW), B+M, 2B, 4B.
Please refer to the acoustic output declaration for each transducer as following pages.

5. Device Description

B-Ultrasound Diagnostic System in a general-purpose, digital ultrasound diagnostic system for abdomen, gynecology, obstetric, urology, and small-parts application.
The system is intended to use for the following type of studies: fetal organ, abdominal, pediatric, small organs, neonatal cephalic, peripheral vascular, and musculo-skeletal (both conventional and superficial). The device is intended to adult, pregnant woman, pediatric and neonate.
The system is a prescription device intended to be used by or on the order of a physician or similar qualified health care professional.
This device is not intended for home use.
Modes of operation include B, M, PWD(PW), B+M, 2B, 4B.
Please refer to the acoustic output declaration for each transducer as following pages.

B-Ultrasound Diagnostic System is a Track 3, diagnostic ultrasound system, which has a main unit and two probes (Broadband convex array probe and Broadband convex array probe), powered by a 14.4V lithium battery, the ultrasonic signal is continuously transmitted at a frequency of 2-12MHz.

The B-Ultrasound Diagnostic System of six functional modules: Power module, Ultrasound front-end module, Keyboard module, Industrial control board, LCD screen, and Interface board. When electrical pulses are applied to the piezoelectric wafer (transducer), it will produce ultrasound waves of a certain frequency, which will enter the human body. Due to the ultrasound

waves traveling through different tissues in the human body with different acoustic impedances (caused by differences in density and ultrasound transmission speed), the reflected echoes generated by the surfaces of different organs in the human body will be different. The reflected echoes of different sizes will be received by the piezoelectric wafer, and then converted into electrical pulse signals. After digital beamforming and other processing, those signals are formed into standard video signals that can be displayed on the monitor screen as cross-sectional images of the organ.

Table 1 Output Range Summary

System: B-Ultrasound Diagnostic System

Transducer: Broadband convex array probe

Item	Mode of Operation			
Global Maximum Output Levels (est.)	B	M	PW	Combined B/M
max $I_{SPTA.3}$	73.47	101.22	604.77	163.47
min $I_{SPTA.3}$	18.37	25.31	151.19	40.87
max MI	1.67	1.67	1.20	1.67
min MI	0.42	0.42	0.30	0.42
max TIS	2.22	0.37	0.72	2.25
min TIS	0.56	0.09	0.18	0.56
max TIB	2.22	0.98	1.67	2.86
min TIB	0.56	0.25	0.42	0.72

Table 2 Output Range Summary

System: B-Ultrasound Diagnostic System

Transducer: Broadband linear array probe

Item	Mode of Operation			
Global Maximum Output Levels (est.)	B	M	PW	Combined B/M
max $I_{SPTA.3}$	94.10	152.58	232.97	497.48
min $I_{SPTA.3}$	23.53	38.15	58.24	124.37
max MI	1.86	1.86	1.86	1.22
min MI	0.46	0.46	0.46	0.30
max TIS	1.84	0.31	1.90	0.88
min TIS	0.46	0.08	0.48	0.22
max TIB	1.84	0.63	2.21	1.74
min TIB	0.46	0.16	0.55	0.43

Table 3 Transducer/Mode Combination Summary

System: B-Ultrasound Diagnostic System

Item	Mode of Operation					
Transducer Model	B	M	PWD	Combined (Specify)		
				2B	4B	B/M
Broadband convex array probe	√	√	√	√	√	√
Broadband line array probe	√	√	√	√	√	√

6. Predicate Device Identification

Predicate Device:

510(k) Number: K170856

Product Name: CMS600P2 B-Ultrasound Diagnostic System

Manufacturer: Contec Medical Systems Co.,Ltd

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1: 2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-37: 2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 62133-2: 2017 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
- ISO 10993-5: 2009 Biological evaluation of medical device - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2010 Biological evaluation of medical devices - Part 10: irritation and skin sensitization
- IEC 62359: 2017 Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields
- IEC TR 60601-4-2: 2016 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and

medical electrical systems

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device (K170856)	Remark
Product Code	IYO; ITX	IYO; ITX	SAME
Regulation No.	21 CFR 892.1560; 21 CFR 892.1570	21 CFR 892.1560; 21 CFR 892.1570	SAME
Class	2	2	SAME
Type of Use	Prescription Use	Prescription Use	SAME
Indication for Use	B-Ultrasound Diagnostic System in a general-purpose, digital ultrasound diagnostic system for abdomen,gynecology, obstetric, urology,and small-parts application. The system is intended to use for the following type of studies: fetal organ, abdominal, pediatric, small organs (Thyroid, Galactophore, Testis), neonatal cephalic, peripheral vascular, and musculo-skeletal (both conventional and superficial). The device is intended to adult, pregnant woman, pediatric and neonate. The system is a prescription device intended to be used by or on the order of a physician or similar qualified health care professional. This device is not intended for home use. Modes of operation include B, M, PWD(PW), B+M, 2B, 4B. Please refer to the acoustic output declaration for each transducer as following pages.	CMS 600P2 B-Ultrasound Diagnostic System in a general-purpose, digital ultrasound diagnostic system for abdomen,gynecology, obstetric, urology,and small-parts application. The system is intended to use for the following type of studies: fetal organ, abdominal, pediatric, small organs, neonatal cephalic, peripheral vascular, and musculo-skeletal (both conventional and superficial). The device is intended to adult, pregnant woman, pediatric and neonate. The system is a prescription device intended to be used by or on the order of a physician or similar qualified health care professional. This device is not intended for home use. Please refer to the acoustic output declaration for each transducer as following pages.	SAME

Table 2 Performance Comparison

ITEM	Proposed Device		Predicate Device (K170856)		Remark
Probe mode	C5~2-80R60-BDC Convex array probe	L12~5-80L40-BDC Line array probe	C3.5-80R60-A16A Convex probe	L7.5-80L40-A16A linear	/

Scan angle/width		60°	45mm	110°	6.3mm	Analyse 1
Maximum number of Active elements for a single pulse		40	40	5	5	Analyse 1
Frequency		2~5MHz	5~12MHz	3.5MHz	7.5MHz	Analyse 1
Number of Element		80	80	80	80	SAME
Size of Element(mm)		0.78*14	0.5*7.1	0.48×7.5	0.5×6.3	Analyse 1
Spacing of element(mm)		0.42	0.2	0.48	0.5	Analyse 1
Array dimensions(mm)		62.4*14	40*7.1	38.4×7.5	40×6.3	Analyse 1
Detect Depth(mm)		≥160	≥70	≥160	≥50	Analyse 1
Resolution (mm)	**Lateral**	≤2(depth≤130) ≤3(130<depth≤160)	≤1(depth≤60)	≤3(Depth≤80) ≤4(80<Depth≤130)	≤2(Depth≤ 40)	Analyse 1
	Axial	≤1(depth≤130)	≤0.5(depth≤50)	≤2(Depth≤80) ≤3(80<Depth≤130)	≤1(Depth≤50)	Analyse 1
Blind Zone(mm)		≤3	≤2	≤5	≤3	Analyse 1
Focus Position		4 focus, adjustable position	4 focus, adjustable position	4 focus, adjustable position	4 focus, position is not adjustable	SAME
Monitor Size		15 inch		10.1 inch		Analyse 2
Display Mode		B, 2B, 4B, M, B/M, PW		B, 2B, BM, M, 4B		Analyse 3
Image gray scale		256 level		256 level		SAME
Image Storage		1086 frame		2048 frame		Analyse 1
Cine Loop		1086 frame		600 frame		Analyse 1
Image Flip		Up/down, left/right, black/white		Up/down, left/right, black/white		SAME
Image Process		Gamma (gray scale) correction, tissue harmonic imaging, histogram, local magnification		Gamma (gray scale) correction, tissue harmonic imaging, histogram, local magnification		SAME
Measurement		Distance, circumference, area, volume, pregnant age, fetal weight, expected date		Distance, circumference, area, volume, heart, pregnant age, fetal weight, expected date		SAME
Notation		Date, time, name, No., sex, age, doctor, hospital name, probe frequency, etc.		Date, time, name, No., sex, age, doctor, hospital name, probe frequency, etc.		SAME
Net weight		6.5 kg		2.3 kg (include probe)		Analyse 2
Power supply		DC 15V; Adapter: 100~240V, 50/60Hz		DC15V; Adapter:100 V~240 V, 50 Hz/60 Hz		SAME
Dimensions(mm)		370mm×360mm×80mm		292 mm(L) × 232 mm(W) × 45 mm(H)		Analyse 2
Configuration		mainframe, transducer(probe)		mainframe, transducer(probe)		SAME
Acoustic Output Parameter	**$I_{SPTA.3}$**	Meet the requirements of Track 3		Meet the requirements of Track 3		SAME
	$I_{SPPA.3}$					
	MI					
Skin Contacted Material		Plastic housing of probe (ABS)		Probe Cover (ABS)		SAME
		Acoustic Len (RTV)		Acoustic Lens (Silicone elastomer)		
Operation Environment		Temperature: +5℃~ +40℃ Relative humidity: ≤80% Atmosphere pressure: 700 hPa ~ 1060 hPa		Temperature: +10℃~ +40℃ Relative humidity: 30%~ 75% Atmosphere pressure: 700 hPa ~ 1060 hPa		Analyse 2

Storage Environment	Temperature: -10℃~ +55℃ Relative humidity: ≤93%, without condensation Atmosphere pressure: 700 hPa ~ 1060 hPa	Temperature: -10℃~+55℃, Relative Humidity: ≤93%, no condensation. Atmosphere pressure: 700 hPa ~ 1060 hPa	SAME
Sterile	No	No	SAME
Single Use	No	No	SAME

Table 3 Applied Standards Comparison

ITEM	Proposed Device	Predicate Device (K170856)	Remark
Biocompatibility	ISO10993-5 & ISO10993-10	ISO10993-5 & ISO10993-10	SAME
Electrical Safety	IEC60601-1	IEC60601-1	SAME
EMC	IEC60601-1-2	IEC60601-1-2	SAME
Performance	IEC 60601-2-37	IEC 60601-2-37	SAME

The subject device has same classification information, same intended use, same indication for use, similar product design, similar specification, same safety elements, similar applied Standards as predicate device.

The differences are included as followings:

Analyse 1:

The device and predicate device have difference in performance specification, such as scan/angle/width, maximum number of active elements for a single pulse, frequency, size of element, spacing of element, array dimensions, detect depth, resolution, blind zone, image storage, cine loop. But the propose device have tested for measurement accuracy by accuracy testing and software validation, so these difference can prove the effectiveness of propose device.

The proposed device has tested according with the safety standard IEC 60601-1, IEC 60601-1-2 for the safety. The proposed device has tested according with the accuracy report, IEC 60601-2-37 report, IEC 62359 report for the effectiveness. The proposed device has tested according with the ISO 10993 series standard for the Biocompatibility.

Therefore, the differences above between the proposed device and predicate device do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety. No new technology is applied in the subject device. Most of the main aspects on effectiveness and safety between the proposed device and predicate device are same. The differences are slight so that no substantial influence on the effectiveness and safety.

Analyse 2:

The proposed device is different in monitor size, net weight, dimensions and operation environment from the predicate device. However, these differences are just in physical specification and will not raise any issues in safety and effectiveness. By complying with IEC 60601-1, the mechanical performance of the proposed device is determined to be accepted. Therefore, these differences will not affect safety and effectiveness of the proposed device.

Analyse 3:

The proposed device is different in display mode from the predicate device. The proposed device has tested according with the accuracy report, IEC 60601-2-37 report, IEC 62359 report for the effectiveness. So we believe that this difference will not raise any risks in safety and effectiveness, both the proposed device and predicate device are safe and effective.

10. Substantially Equivalent (SE) Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device (K170856).