Contec Medical System Co., Ltd. November 17, 2017
% Mr. Ray Wang
General Manager
Beijing Believe Technology Service Co., Ltd.
5-1206, Build 332, DaFangJu, No.25 BanBiDian Road
LiYuan Town, TongZhou District, Beijing, 101121
CHINA

Re: K170856
Trade/Device Name: CMS600P2 B-Ultrasound Diagnostic System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: October 18, 2017
Received: October 23, 2017

Dear Mr. 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 (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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170856

Device Name
CMS600P2 B-Ultrasound Diagnostic System

Indications for Use *(Describe)*
CMS600P2 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, transvaginal, 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

System: CMS600P2 B-Ultrasound Diagnostic System

Transducer: _____

Intended Use:Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) B/M	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N				N	
	Abdominal	N	N				N	
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N				N	
	Small Organ (Specify)	N	N				N	Note 2,3
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	N	N				N	
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal(**Conventional**)	N	N				N	
	Musculo-skeletal (**Superficial**)	N	N				N	
	Intravascular							
	Other (Specify)	N	N				N	Note 1
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N				N	
	Other (Specify)							

Additional comment:Combined mode : B/M

Note 1:urology: prostate and vesica urinaria; Note 2: Thyroid Gland; Note 3: Hip Joint

N = new indication; P = previously cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

System: CMS600P2 B-Ultrasound Diagnostic System
Transducer: C3.5-80R60-A16A
Intended Use:Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) B/M	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N				N	
	Abdominal	N	N				N	
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N				N	
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal(**Conventional**)	N	N				N	
	Musculo-skeletal (**Superficial**)	N	N				N	
	Intravascular							
	Other (Specify)	N	N				N	Note 1
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

Additional comment:Combined mode : B/M
Note 1:urology: prostate and vesica urinaria
N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

System: CMS600P2 B-Ultrasound Diagnostic System
Transducer: E6.5-80R13-A16A
Intended Use:Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	N	N				N	
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

Additional comment:Combined mode : B/M

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

System: CMS600P2 B-Ultrasound Diagnostic System
Transducer: L7.5-80L40-A16A
Intended Use:Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)	N	N				N	Note 2,3
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N				N	
	Other (Specify)							

Additional comment:Combined mode : B/M
Note 2: Thyroid Gland Note 3: Hip Joint

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Tab #4 510(k) Summary

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

The assigned 510(k) Number: K170856

1. Date of Preparation: 11/18/2017

2. Sponsor Identification

Contec Medical System Co., Ltd.
No.112 Qinhuang West Street, Economic & Technical Development Zone,
Qinhuangdao, Hebei, 066004, China.
Establishment Registration Number: 3006979678

Contact Person: Xueyong Li
Position: Quality Manager
Tel: 86-355-8015490
Fax: 86-355-8015490
Email: lxy1011@163.com

3. Designated Submission Correspondent

Mr. Ray Wang

Beijing Believe Technology Service Co., Ltd.
5-1206, Build 332, DaFangJu, No.25 BanBiDian Rd.,
LiYuan Town, TongZhou District, Beijing, 101121, China

Tel: +86-18910677558
Fax: +86-10-52214696
Email: **ray.wang@believe-med.com**

4. Identification of Proposed Device

Trade Name: CMS600P2 B-Ultrasound Diagnostic System
Common Name: Diagnostic Ultrasound System with Accessories
Model(s): CMS600P2

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

Review Panel:Radiology;

Intended Use Statement:

CMS600P2 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, transvaginal, 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.

Device Description

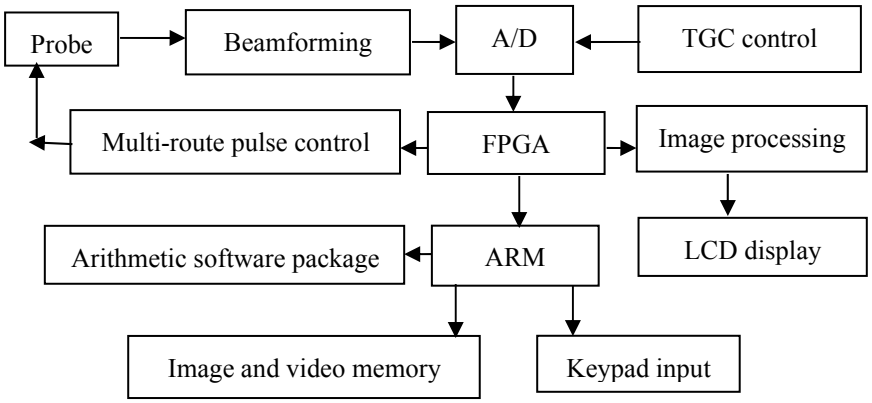
- The apparatus is high resolution ultrasound diagnostic system, which adopts digital beam forming(DBF), real-time dynamic aperture(RDA), real-time dynamic beam apodization (DRA), real-time dynamic receive focusing (DRF), digital-control dynamic frequency scanning (DFS), frame correlation etc. technologies. The image is clear, stable, and high resolution.
- It adopts embedded operating system, which greatly improve the product security and compatibility, and enhance the data processing ability.
- The apparatus is taken more conveniently for its humane operation interface and management system, flexible expansibility and compatibility, pop-up menu and keyboard design.
- Users can chose different kinds of display modes,such as:B, 2B, 4B, BM, M. Image real-time, freeze, memory, calling up and large capability cine loop can be realized; the device possesses multilevel scanning depth, dynamic range, sound output power and focus number, focus space, focus position adjusting etc. functions.
- With controllable frame correlation, gamma correction, image reversing, histogram, depth advance, zoom magnification, no distortion real-time part magnification etc. image processing functions. It is convenient for choice of optimal diagnostic image with image pigeonhole, browse, management functions. Measure, calculation, and report features are provided to facilitate image measurement.

- The device supports linear probe and convex probe. The frequency of the device is 2.0 MHz-10.0 MHz. It has extensive application that is suitable for clinic diagnosis, such as abdomen, obstetrics, gynecology, small organs, cardiology and urology etc. .
- The device is consist of three parts: mainframe, transducer(probe), adapter.
- The transducers provided are listed below in table 7-1, the specification of the system and transducers please refer to Tab 9 section 7 Technical Specifications. The picture and design drawing of the subject device and its transducer is presented in Tab 9 section 2 Device Illustration.

Table 7-1 Transducer List

Transducer Model	Type	Frequency	Application
C3.5-80R60-A16A	convex probe	3.5 MHz	Abdomen, obstetrics, urology
L7.5-80L40-A16A	linear probe	7.5 MHz	small organs
E6.5-80R13-A16A	endo-vaginal probe	6.5 MHz	Gynecology and transvaginal

Fig 7-1 Working Frame of CMS600P2



5. Identification of Predicate Device(s)

Predicate Device ：

510(k) Number: K081873
Product Name: Full Digital Ultrasound Diagnostic Device
Model Name: EMP-2100
Manufacturer:
Shenzhen Emperor Electronic Technology Co., Ltd.

6. 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:

a. IEC 60601-1:2005+A1:2012, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance
b. IEC 60601-1-2:2007, Medical Electrical Equipment-Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility-Requirements And Tests
c. IEC 60601-2-37:2007 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
d. IEC61157:1992 Requirements for the Declaration of the Acoustic Output of Medical Ultrasound Diagnostic Apparatus
e. ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity.
f. ISO 10993-10:2010 Standard, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 7-1 Comparison of Technology Characteristics

Item	Proposed Device(s)	Predicate Device(s)	Remark
Device name	*CMS600P2 B-Ultrasound Diagnostic System*	EMP-2100 Full Digital Ultrasound Diagnostic Device	/
Classification Name	*System, Imaging, Pulsed echo,* *Ultrasonic* *Transducer, Ultrasonic, Diagnostic*	System, Imaging, Pulsed echo, Ultrasonic Transducer, Ultrasonic, Diagnostic	SE
Product Code	IYO ITX	IYO ITX	SE
Regulation Number	892.1560 892.1570	892.1560 892.1570	SE
Comparison Statement	**The proposed device has same classification information as the predicate device.**		
Intended Use	CMS600P2 B-Ultrasound Diagnostic System in a general-purpose, digital ultrasound diagnostic system for abdomen,gynecology, obstetric, urology,small-parts, and cardiology application. The system is intended to use for the following type of studies: fetal organ, abdominal, pediatric, small organs, neonatal cephalic, cardiac, transvaginal, 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	EMP-2100 Full Digital Ultrasound Diagnostic Device in a general-purpose, digital ultrasound diagnostic system for abdomen,gynecology,obstetric,urology,small-parts,and cardiology application. The system is intended to use for the following type of studies:fetal organ, abdominal, pediatric, small organs, Neonatal cephalic, cardiac, transvaginal, 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	SE

		the order of a physician or similar qualified health care professional. This device is not intended for home use.			on the order of a physician or similar qualified health care professional. This device is not intended for home use.				
Comparison Statement		**The proposed device has similar intended use as the predicate device.**							
Main Unit Technical Specifications									
Probe mode		C3.5-80R60 -A16A Convex probe	L7.5-80L40-A16A linear	E6.5-80R13-A16A endo-vaginal	C128-50 Convex	L096-42C Linear	C080-13G Micro Convex	C096-20A Micro Convex	/
Scan angle/width		110°	6.3mm	114.6°	128°	40mm	120°	88°	Analyse1
Maximum number of Active elements for a single pulse		5	5	5	32	32	32	32	Analyse1
Frequency		3.5MHz	7.5MHz	6.5MHz	3.5MHz	6.5MHz	6.5MHz	3.5MHz	Analyse1
Number of Element		80	80	80	128	96	80	96	Analyse1
Size of Element(mm)		0.48x7.5	0.5x6.3	0.33x7.3	0.41x13.4	0.34 x8.2	0.26 x8.2	0.24 x11.4	Analyse1
Spacing of element(mm)		0.48	0.5	0.33	0.49	0.42	0.34	0.32	Analyse1
Array dimensions(mm)		38.4x7.5	40x6.3	26.4x7.3	62.8x13.4	40.3 x8.2	27.2 x8.2	30.7 x11.4	Analyse1
Detect Depth(mm)		≥160	≥50	≥40	≥200	≥90	≥90	≥90	Analyse1
Resolution (mm)	Lateral	≤3(Depth≤80) ≤4(80<Depth ≤130)	≤2(Depth≤ 40)	≤2(Depth ≤30)	≤3(depth≤80)≤4(80 ＜ depth≤130)	≤2(depth ≤60)	≤2(depth ≤60)	≤2(depth ≤40)	Analyse1
	Axial	≤2(Depth≤80) ≤3(80<Depth	≤1(Depth ≤50)	≤1(Depth ≤40)	≤1(80＜ depth≤130)	≤0.5 (depth≤80)	≤0.5 (depth≤60)	≤0.5 (depth≤40)	Analyse1

		≤130)							
Blind Zone(mm)		≤5	≤3	≤4	≤3	≤3	≤3	≤3	Analyse1
Focus Position		4 focus, adjustable position	4 focus, position is not adjustable		4-steps dynamic focusing with variable aperture and lens focusing				Analyse1
Monitor Size		10.1 inch			10 inch				SE
Display Mode		B, 2B, BM, M, 4B			B, B+B, B+M, M, 4B				SE
Image gray scale		256 level			256				SE
Image Storage		2048 frame			16				Analyse1
Cine Loop		600 frame			256 frame				Analyse1
Image Flip		Up/down, left/right, black/white			Up/down, left/right				Analyse1
Image Process		Gamma (gray scale) correction, tissue harmonic imaging, histogram, local magnification			Dynamic range, edge enhancement, frame correlation, smooth, IP, gray map,r-correction, rejection				Analyse1
Measurement		Distance, circumference, area, volume, heart, pregnant age, fetal weight, expected date			Distance, circumference, area,volume, histogram, profile, time velocity heart rate				Analyse1
Notation		Date, time, name, No., sex, age, doctor, hospital name, probe frequency, etc.			Date, Time, Name, Sex, Age, Doctor, Hospital name, probe frequency, etc.				SE
Net weight		2.3 kg (include probe)			10kg				SE
Power supply		DC15V; Adapter:100 V~240 V, 50 Hz/60 Hz			AC 100-240V, 47-60Hlz				Analyse2
Dimensions(mm)		292 mm(L) × 232 mm(W) × 45 mm(H)			365 (height) X292 (width) X380 (depth)				SE
Configuration		mainframe, transducer(probe)			mainframe, transducer(probe)				SE
Acoustic Output Parameter	Ispta. 3	Meet the requirements of Track 3			Meet the requirements of Track 1				Analyse1
	Isppa. 3								
	MI								
Skin Material	Contacted	Probe Cover (ABS)			Probe Cover (ABS)				SE
		Acoustic Lens (Silicone elastomer)			Acoustic Lens (Silicone elastomer)				SE

Operation Environment	Temperature: +10℃~ +40℃ Relative humidity: 30%~ 75% Atmosphere pressure: 700 hPa ~ 1060 hPa	Temperature 5°C -40°C , relative humidity up to 90%RH air pressure 70-106Kpa	SE
Storage environment	Temperature: -10℃~+55℃, Relative Humidity: ≤93％, no condensation. Atmosphere pressure: 700 hPa ~ 1060 hPa,	Temperature -5-40°C , relative humidity up to 90%RH (no water I drop) air pressure 70-106Kpa	SE
Sterile	No	No	SE
Single Use	No	No	SE
Comparison Statement:	**The proposed device has the similar main unit specifications with the predicate device.**		
Applied Standards:			
Biocompatibility	ISO10993-5&ISO10993-10	ISO10993-5&ISO10993-10	SE
Electrical Safety	IEC60601-1	IEC60601-1	SE
EMC	IEC60601-1-2	IEC60601-1-2	SE
Performance	IEC 60601-2-37;IEC61157	UD2	Analyse1
Comparison Statement	**The proposed probe has similar applied Standards with the predicate device.**		

9. Substantially Equivalent (SE) Conclusion

SE Analysis :

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 elements for a single pulse, frequency, number of element, size of element, spacing of element, array dimensions, detect depth and resolution. 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, IEC60601-1-2 for the safety.The proposed device has tested according with the accuracy report, IEC60601-2-37 report, IEC61157 Acoustic Output 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： Although the Power supply specifications of CMS600P2 is different from the predicate device,but both the predicate device and the proposed device has passed the IEC60601-1 safety test, we believe these differences will not affect the effectiveness and safety compared with the predicate device.

Conclusion: The proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device. Therefore, the subject device is determined as safe and effectiveness.