Wuxi Hisky Medical Technologies Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
5-402, Building #27, No. 56, LiangXiang East Rd.
FangShan District
Beijing, Beijing 102401
CHINA

March 17, 2020

Re: K200136
Trade/Device Name: Shear Wave Quantificational Ultrasound Diagnostic System
Model(s): FT9000, FT100, Mini800
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX, IYN
Dated: January 17, 2020
Received: January 21, 2020

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 (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)*
K200136

Device Name
Shear Wave Quantificational Ultrasound Diagnostic System
Model(s): FT9000, FT100, Mini800

Indications for Use *(Describe)*

Shear Wave Quantificational Ultrasound Diagnostic System (Models: FT9000, FT100 and Mini800), Transient Elastography based device, is intended to provide 50Hz shear wave speed measurements and estimates of tissue stiffness as well as Ultrasound Attenuation Parameter (UAP) in internal structures of the body.

Shear Wave Quantificational Ultrasound Diagnostic System (Models: FT9000, FT100 and Mini800), is indicated for noninvasive measurement in the liver of 50 Hz shear wave speed and estimates of stiffness as well as Ultrasound Attenuation Parameter (UAP).

The shear wave speed and stiffness, and UAP may be used as an aid to diagnosis and monitoring of patients with liver disease, as part of an overall assessment of the liver.

Shear Wave Quantificational Ultrasound Diagnostic System (Models: FT9000), is intended for general purpose pulse echo ultrasound imaging and Doppler flow analysis of the human body. It can be used in the following applications: Abdominal, including location of the liver.

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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Tab #7 510(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: K200136

1. Date of Preparation: 03/09/2020

2. Sponsor

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3. Submission Correspondent

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Identification of Proposed Device

Trade Name: Shear Wave Quantificational Ultrasound Diagnostic System
Common Name: Diagnostic Ultrasound System with Accessories
Model(s): FT9000, Mini800, FT100

Regulatory Information
Classification Name: 1) Ultrasonic Pulsed Echo Imaging System; 2) Diagnostic Ultrasound Transducer; 3) Ultrasonic Pulsed Doppler Imaging System;
Classification:II
Product Code: IYO & ITX & IYN
Regulation Number:21 CFR 892.1550 & 21 CFR 892.1560 & 21 CFR 892.1570
Review Panel: Radiology;

Indication For Use Statement:

Shear Wave Quantificational Ultrasound Diagnostic System (Models: FT9000, FT100 and Mini800), Transient Elastography based device, is intended to provide 50Hz shear wave speed measurements and estimates of tissue stiffness as well as Ultrasound Attenuation Parameter (UAP) in internal structures of the body.

Shear Wave Quantificational Ultrasound Diagnostic System (Models: FT9000, FT100 and Mini800), is indicated for noninvasive measurement in the liver of 50 Hz shear wave speed and estimates of stiffness as well as Ultrasound Attenuation Parameter (UAP).

The shear wave speed and stiffness, and UAP may be used as an aid to diagnosis and monitoring of patients with liver disease, as part of an overall assessment of the liver.

Shear Wave Quantificational Ultrasound Diagnostic System (Models: FT9000), is intended for general purpose pulse echo ultrasound imaging and Doppler flow analysis of the human body. It can be used in the following applications: Abdominal, including location of the liver.

4. Device Description

The Shear Wave Quantificational Ultrasound Diagnostic System, Models: FT9000, FT100 and Mini800, iLivTouch brand, is a general purpose, mobile, software-controlled, diagnostic ultrasound system. FT9000 is equipped with two probes, a fibrosis scanning probe used in elastography mode and an imaging probe used in imaging mode. The fibrosis scanning probe is used for elasticity measurement while the imaging probe is a convex probe used for ultrasound imaging. But the model FT100 and Mini800 is equipped with only one fibrosis scanning probe.FT100 and Mini800 have the same appearance structure and hardware，but the software is different.

Under elastography mode, the system uses transient elastography to measure shear wave speed non-invasively and estimates of tissue stiffness as well as Ultrasound Attenuation Parameter (UAP) in internal structures of the body. A mechanical vibrator produces low-amplitude shear waves at 50 Hz that travel through the skin and intercostal space into the liver. The propagation speed of the shear wave is measured using ultrasound at 2.5 MHz.

Under imaging mode, the system acquires and displays ultrasound images in B, B/B, B/D, B/C (CFM), B/C/D (CPWD) modes. The system uses convex array probe with a frequency range of 2.1MHz to 5 MHz on abdomen for general purpose pulse echo ultrasound imaging and Doppler flow analysis of the human body. The ultrasonic imaging also helps to find a proper location for the transient elastography examination.

Table 7-1 Accessories List of FT9000

Name	Qty.	Usage
Imaging probe	1	To determine the test zone
Fibrosis Scanning probe	1	To test the liver stiffness and UAP
Main unit	1	To calculate the liver stiffness with acquired data
Power Cord	1	To energize the main unit
Footswitch	1	To start the examination
Fuse T3.15 AH250V	2	Overcurrent protection
Protective earth wire	1	To connect the system with the ground

Table 7-2 Accessories List of FT100 and Mini800

Name	Qty.	Usage
Fibrosis scanning probe	1	To test the liver stiffness and UAP
Main unit	1	To calculate the liver stiffness with acquired data
Probe holder	1	To hold the probe
AC/DC adapter	1	To energize the main unit
Foot switch	1	To start the examination
Keyboard (optional)	1	For ease of operate
Mouse (optional)	1	For ease of operate

Table 7-3 Transducer List

Product model	Transducer Model	Type	Frequency	Application
FT9000	FT-2.5D9	Round probe	2.5MHz(deviation≤±15%)	Liver, elasticity measurement
	FT-3.5R65	convex probe	3.5MHz(nominal), 2.1, 2.5, 3.1, 5.0 (broadband frequency)	Abdomen, general purpose Pulse echo ultrasound imaging and Doppler flow analysis
FT100	FT-2.5D9	Round probe	2.5MHz(deviation≤±15%)	Liver, elasticity measurement
Mini800	XW-01	Round probe	2.5MHz(deviation≤±15%)	Liver, elasticity measurement
Note: The XW- 01 probe for Mini800 is exactly the same as the FT- 2.5D9 probe for FT9000/FT100. And all materials and manufacturing processes to produce final finished form of XW-01 are identical to FT-2.5D9. .				

Fig 7-1 Working Frame of (Models: FT9000)

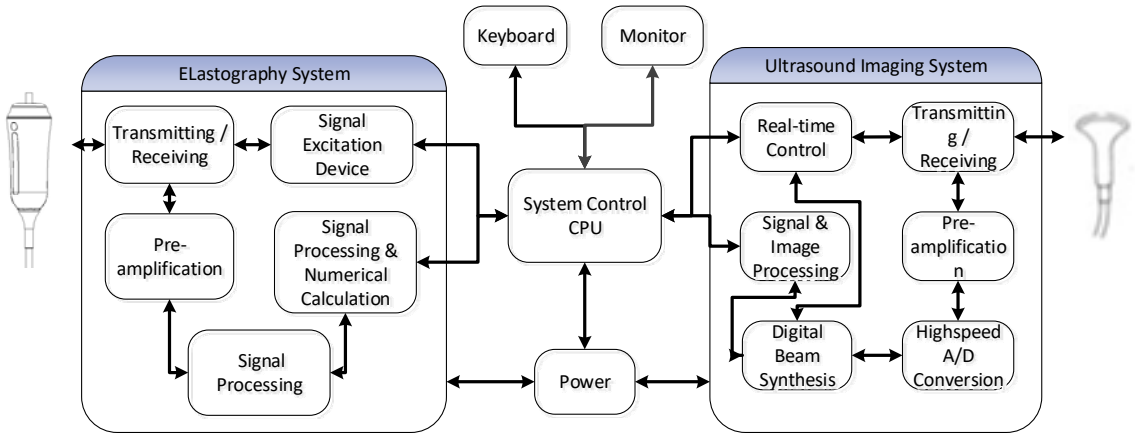
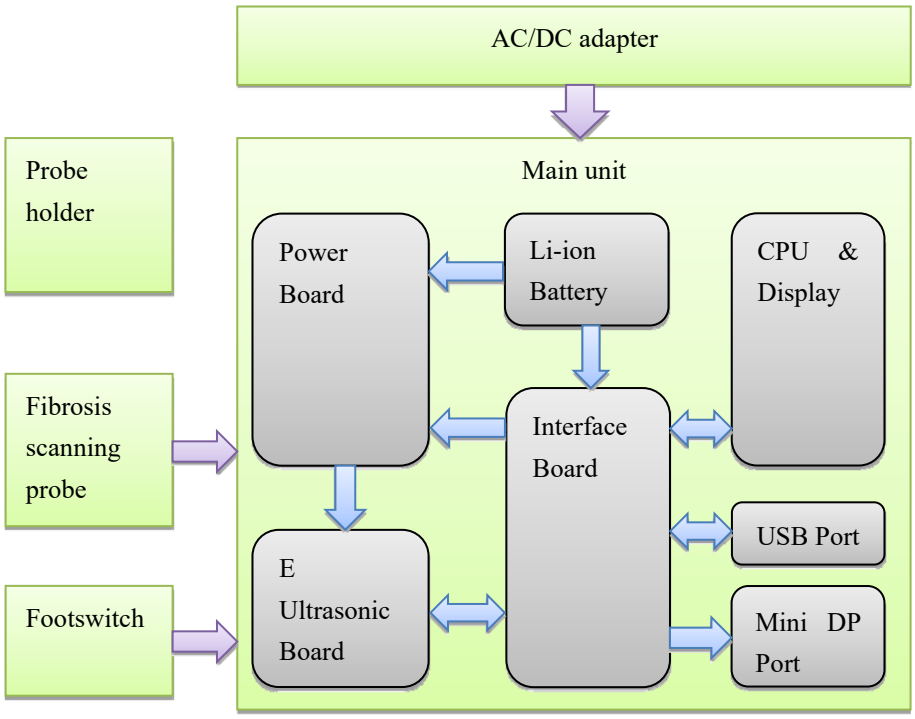


Fig 7-2 Working Frame of (Models: FT100 and Mini800)



5. Identification of Predicate Device

Primary Predicate Device:
510(k) Number: K173595
Product Name: Shear Wave Quantificational Ultrasound Diagnostic System
Manufacturer: Wuxi Hisky Medical Technologies Co., Ltd.

Secondary Predicate Device:

510(k) Number: K181547
Product Name: FibroScan® Family Of Products
Model Name: FibroScan® 502 Touch
Manufacturer: Echosens

The reason we selected the secondary device is that the Indication For Use of subject device covered both primary and secondary predicate device.

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:

- IEC 60601-1:2005+A1:2012, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance;
- NEMA UD 2-2004 (R2009), Acoustic Output Measurement Standard For Diagnostic Ultrasound Equipment Revision 3. (Radiology).
- IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ISO 10993-5 Third Edition 2009-06-01, Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity. (Biocompatibility)
- ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization. (Biocompatibility)

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 7-4 Comparison of Technology Characteristics to Primary Predicate Device

Item	Proposed Device(s)	Primary Predicate Device (K173595)	remark
Device name	Models: FT9000, FT100 and Mini800 Shear Wave Quantificational Ultrasound Diagnostic System	FT9000 Shear Wave Quantificational Ultrasound Diagnostic System	/
Classification Name	1) Ultrasonic Pulsed Echo Imaging System; 2) Diagnostic Ultrasound Transducer; 3) Ultrasonic Pulsed Doppler Imaging System;	1) Ultrasonic Pulsed Echo Imaging System; 2) Diagnostic Ultrasound Transducer; 3) Ultrasonic Pulsed Doppler Imaging System;	Same
Product Code	IYO ITX IYN	IYO ITX IYN	Same
Regulation Number	892.1550; 892.1560; 892.1570;	892.1550; 892.1560; 892.1570;	Same
Intended Use	Shear Wave Quantificational Ultrasound Diagnostic System (Models: FT9000, FT100 and Mini800), Transient Elastography based device, is intended to provide 50Hz shear wave speed measurements and estimates of tissue stiffness as well as Ultrasound Attenuation Parameter (UAP) in internal structures of the body. Shear Wave Quantificational Ultrasound Diagnostic System (Models: FT9000, FT100 and Mini800), is indicated for noninvasive measurement in the liver of 50 Hz shear wave speed and estimates of stiffness as well as Ultrasound Attenuation Parameter (UAP). The shear wave speed and stiffness, and UAP may be used as an aid to diagnosis	Shear Wave Quantificational Ultrasound Diagnostic System, Model FT9000, is intended to measure the speed of 50Hz shear wave with 2.5MHz ultrasound wave in the liver. The shear wave speed may be used as an aid to clinical management of patients with liver disease. Shear Wave Quantificational Ultrasound Diagnostic System, Model FT9000, is intended for general purpose pulse echo ultrasound	Analysis 1

	and monitoring of patients with liver disease, as part of an overall assessment of the liver. Shear Wave Quantificational Ultrasound Diagnostic System (Models: FT9000), is intended for general purpose pulse echo ultrasound imaging and Doppler flow analysis of the human body. It can be used in the following applications: Abdominal, including location of the liver.		imaging and Doppler flow analysis of the human body. It can be used in the following applications: Abdominal.	
Probe Types	FT9000	Fibrosis scanning probe FT-2.5D9 an imaging probe FT-3.5R65	Fibrosis scanning probe FT-2.5D9 an imaging probe FT-3.5R65	Same
	FT100	Fibrosis scanning probe FT-2.5D9		
	Mini800	Fibrosis scanning probe XW-01		Analysis 1
Probe frequency	Fibrosis scanning probe (FT-2.5D9):2.5MHz an imaging probe FT-3.5R65：3.5 MHz Fibrosis scanning probe XW-01 Probe (2.5 MHz)		Fibrosis scanning probe (FT-2.5D9):2.5MHz an imaging probe FT-3.5R65：3.5 MHz	Same
Modes of Operation	M-mode A-mode		M-mode A-mode	Same
Applied Standards:				
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	UD2		UD2	Same

Analysis 1:

The Proposed Device(s) is similar to the predicate devices, the difference is very slight, and only in the indications for use (adding UAP functions) and probe models,

a、for the added UAP function, the proposed devices has passed the related performance test (eg UD2 test)；

b、The Proposed Device Mini800 use the different probe, but the probe frequency is same with the Predicate Device, the proposed devices has passed the related

performance test and safety test (eg UD2 test ,IEC60601-1 test ,IEC60601-1-2 test) ;
So the safety and performance of the product can be ensured, so the proposed device is determined to be substantially equivalency with predicate device.

Table 7-5 Comparison of Technology Characteristics to Secondary Predicate Device

Item	Proposed Device(s)			Secondary Predicate Device (K181547)	remark
	FT9000	FT100	Mini800		
Device name	Models: FT9000, FT100 and Mini800 Shear Wave Quantificational Ultrasound Diagnostic System			FibroScan® 502 Touch (Predicate)	/
Classification Name	1) Ultrasonic Pulsed Echo Imaging System; 2) Diagnostic Ultrasound Transducer; 3) Ultrasonic Pulsed Doppler Imaging System;			1) Ultrasonic Pulsed Echo Imaging System; 2) Diagnostic Ultrasound Transducer;	Same
Product Code	IYO ITX IYN			IYO ITX	Same
Regulation Number	892.1550; 892.1560; 892.1570;			892.1560; 892.1570;	Same
Intended Use	Shear Wave Quantificational Ultrasound Diagnostic System (Models: FT9000, FT100 and Mini800), Transient Elastography based device, is intended to provide 50Hz shear wave speed measurements and estimates of tissue stiffness as well as Ultrasound Attenuation Parameter (UAP) in internal structures of the body. Shear Wave Quantificational Ultrasound Diagnostic System			The FibroScan® Family of Products (Models: 502 Touch) is intended to provide 50Hz shear wave speed measurements and estimates of tissue stiffness as well as 3.5 MHz ultrasound coefficient of attenuation (CAP: Controlled Attenuation Parameter) in internal structures of the body. FibroScan® Family of Products (Models: 502 Touch) is	Same

	(Models: FT9000, FT100 and Mini800), is indicated for noninvasive measurement in the liver of 50 Hz shear wave speed and estimates of stiffness as well as Ultrasound Attenuation Parameter (UAP). The shear wave speed and stiffness, and UAP may be used as an aid to diagnosis and monitoring of patients with liver disease, as part of an overall assessment of the liver. Shear Wave Quantificational Ultrasound Diagnostic System (Models: FT9000), is intended for general purpose pulse echo ultrasound imaging and Doppler flow analysis of the human body. It can be used in the following applications: Abdominal, including location of the liver.			indicated for noninvasive measurement in the liver of 50 Hz shear wave speed and estimates of stiffness as well as 3.5 MHz ultrasound coefficient of attenuation (CAP: Controlled Attenuation Parameter). The shear wave speed and stiffness, and CAP may be used as an aid to diagnosis and monitoring of adult patients with liver disease, as part of an overall assessment of the liver. Shear wave speed and stiffness may be used as an aid to clinical management of pediatric patients with liver disease.	
Imaging modes	A-mode M-mode Transient Elastography / Shear Wave			A-mode M-mode Transient Elastography / Shear Wave	Same
Ultrasound Source	Piezoelectric ultrasound source			Piezoelectric ultrasound source	Same E
Probe	FT-2.5D9 Probe (2.5 MHz) FT-3.5R65(3.5 MHz)	FT-2.5D9 Probe (2.5 MHz)	XW-01 Probe (2.5 MHz)	S+ Probe (5 MHz) (single element ultrasound transducer)	Analysis 2
Elastography mode	Transient Elastography			Vibration-controlled Transient ElastographyTM	Same E
Source of Mechanical Vibration	External electromechanical Vibrator			External electromechanical Vibrator	Same
Shear Wave Speed	Post-processing			Post-processing	Same

Determination					
TE mode	Shear wave speed measurements and tissue stiffness			Shear wave speed measurements and tissue stiffness	Same
TE display	Shear wave speed (0.8-5.2 m/s) Stiffness (2.0-80 kPa) Interquartile range (IQR) and IQR/median ratio			Shear wave speed (0.8-5.0 m/s) Stiffness (2.0-75 kPa) Interquartile range (IQR) and IQR/median ratio	Analysis 2
Bias	(-4.7%) - (2.4%)	(-2.1%) – (3.5%)	(-5.3%)– (1.2%)	(-14.3%) – (3.6%)	Analysis 2
Precision	(0.0%) – (1.6%)	(0.0%) – (3.8%)	(0.0%) – (1.8%)	(0.2%) – (1.9%)	Analysis 2
CAP/UAP display	UAP (90-450 dB/m) Interquartile range (IQR) and IQR/median ratio			CAP (100-400 dB/m) Interquartile range (IQR) and IQR/median ratio	Analysis 2
Bias	(-3.3%) – (2.0%)	(-1.6%) – (6.5%)	(-6.9%) - (4.8%)	(0.0%) – (10.0%)	Analysis 2
Precision	(0.2%) – (1.5%)	(0.3%) – (2.0%)	(0.2%) – (2.0%)	(0.0%) – (1.0%)	Analysis 2
Applied Standards:					
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 UD2			IEC60601-2-37 UD2	Same

Analysis 2:

The Proposed Device(s) is similar to the predicate devices, the difference is very slight, and only in the probe frequency,the related parameters of TE mode and CAP/UAP display, but the proposed devices has passed the related performance test and safety test (eg UD2 test ,IEC60601-1 test ,IEC60601-1-2 test，measurement accuracy by accuracy testing and software validation)，the safety and performance of the product can be ensured，so the safety and performance of the product can be ensured, so the

proposed device is determined to be substantially equivalency with predicate device.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.

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