



May 2, 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: K232908

Trade/Device Name: Color Doppler Ultrasound Diagnostic System (CMS1700B), Color Doppler  
Ultrasound Diagnostic System (CMS1700C)

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic Pulsed Doppler Imaging System

Regulatory Class: Class II

Product Code: IYN, ITX, IYO

Dated: September 18, 2023

Received: September 19, 2023

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](mailto: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  
and Radiation Therapy Devices

OHT8: Office of Radiological Health

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K232908

Device Name

Color Doppler Ultrasound Diagnostic System (CMS1700B);

Color Doppler Ultrasound Diagnostic System (CMS1700C)

Indications for Use (Describe)

The Color Doppler Ultrasound Diagnostic System is a general-purpose ultrasound system. It is intended for use by, or under the direction of a qualified and trained physician for ultrasound imaging, measurement, display and analysis of the human body and fluid. The device is intended for use in a hospital environment.

The systems support the following clinical applications:

Ultrasound examination and diagnosis of abdomen, obstetrics, gynecology, small organ (Thyroid, Galactophore, Testis) and cardiac. Modes of operation include: 3D Imaging mode, B, M, PW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Combined modes: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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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510(k) Summary

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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: K232908

1. Date of Preparation: 04/26/2024

2. Sponsor Identification

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3. Designated Submission Correspondent

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510(k) Summary

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## 4. Identification of Proposed Device

Trade Name: Color Doppler Ultrasound Diagnostic System

Common Name: Color Doppler Ultrasound Diagnostic System

Model(s): CMS1700B,CMS1700C

## Regulatory Information

Classification Name: System, Imaging, Pulsed Doppler, Ultrasonic;System, Imaging, Pulsed Echo, Ultrasonic;Transducer, Ultrasonic, Diagnostic

Classification:II

Product Code:IYN&IYO & ITX

Regulation Number:21 CFR 892.1550&892.1560 & 21 CFR 892.1570

Review Panel:Radiology;

## Indication For Use Statement:

The Color Doppler Ultrasound Diagnostic System is a general-purpose ultrasound system. It is intended for use by, or under the direction of a qualified and trained physician for ultrasound imaging, measurement, display and analysis of the human body and fluid. The device is intended for use in a hospital environment.

The systems support the following clinical applications:

Ultrasound examination and diagnosis of abdomen, obstetrics, gynecology, small organ (Thyroid, Galactophore, Testis) and cardiac. Modes of operation include: 3D Imaging mode, B, M, PW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Combined modes: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

## 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. abundant image processing functions. It is convenient for choice of optimal diagnostic image with perfect image pigeonhole, browse, management functions. Measure, calculation, and report are even complete and convenient with powerful measure software package and perfect measurement.
- The device supports linear probe and convex probe. It has extensive application that is

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suitable for clinic diagnosis, such as abdomen, obstetrics, gynecology, small organs, cardiology etc. .

Table1 Transducer List

Device Model	Transducer Model	Type	Frequency	Applicable clinical part	Radius of curvature or array length
CMS1700B	C5~2-80R60-BDC	convex array probe	2.0MHz—5.0MH	Abdomen	R=60
CMS1700B	L12~5-80L40-BDC	linear array probe	6.0MHz—12.0MHz	Shallow surface, Small Organs (Thyroid, Galactophore, Testis)	L=45
CMS1700C	C5~2-128R60-BEB	convex array probe	2.0MHz—5.0MH	Abdomen	R=60
CMS1700C	L12~5-128L40-BEB	linear array probe	6.0MHz—12.0MHz	Shallow surface, Small Organs (Thyroid, Galactophore, Testis)	L=45

**Acoustic output reporting table**

System Model:CMS1700B

Transducer Model:C5~2-80R60-BDC

Global Maximum Output Levels	Mode of operation						
	B	M	B+M	PW	B+PW	B+CF/B+PDI/B+DPDI	B+CF+PW/B+PDI+PW/B+DPDI+PW
Max $ISPTA.3(mW/cm^2)$	61.54	109.23	164.46	642.45	671.60	172.05	716.90
Min $ISPTA.3(mW/cm^2)$	15.36	27.31	41.10	160.61	167.90	43.01	179.22
Max MI	1.51	1.51	1.51	1.17	1.51	1.51	1.51
Min MI	0.38	0.38	0.38	0.29	0.38	0.38	0.38
Max TIS	3.93	0.73	4.27	1.14	2.65	0.77	0.72
Min TIS	0.98	0.18	1.07	0.29	0.66	0.77	0.72
Max TIB	0.93	1.55	5.08	3.65	5.17	3.10	5.36
Max TIB	0.98	0.39	1.27	0.91	1.29	0.77	1.34

Transducer Model:L12~5-80L40-BDC

Global Maximum Output Levels	Mode of operation						
	B	M	B+M	PW	B+PW	B+CF/B+PDI/B+DPDI	B+CF+PW/B+PDI+PW/B+DPDI+PW
Max $ISPTA.3(mW/cm^2)$	82.07	77.32	150.07	559.35	601.81	185.20	718.53
Min $ISPTA.3(mW/cm^2)$	20.52	19.33	37.52	139.84	150.45	46.30	179.63
Max MI	1.58	1.58	1.58	1.45	1.58	1.58	1.58
Min MI	0.39	0.39	0.39	0.36	0.39	0.39	0.39
Max TIS	0.80	0.11	0.82	0.64	0.93	0.67	1.18

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Min TIS	0.20	0.03	0.20	0.16	0.23	0.17	0.30
Max TIB	0.80	0.32	1.03	1.72	2.04	0.67	2.29
Max TIB	0.20	0.08	0.26	0.43	0.51	0.17	0.57

System Model:CMS1700cB

Transducer Model:C5~2-128R60-BEB

Global Maximum Output Levels	Mode of operation						
	B	M	B+M	PW	B+PW	B+CF/B+PDI/B+DPDI	B+CF+PW/B+PDI+PW/B+DPDI+PW
Max $I_{SPTA.3(mW/cm^2)}$	47.94	135.6	177.84	610.21	627.18	220.34	717.37
Min $I_{SPTA.3(mW/cm^2)}$	11.98	33.92	44.46	152.55	156.80	55.09	179.34
Max MI	1.60	1.60	1.60	1.33	1.60	1.60	1.60
Min MI	0.40	0.40	0.40	0.33	0.40	0.40	0.40
Max TIS	2.76	0.47	0.291	0.83	1.60	2.31	1.75
Min TIS	0.69	0.12	0.73	0.21	0.40	0.58	0.44
Max TIB	2.76	1.21	3.64	3.96	4.76	2.31	4.88
Max TIB	0.69	0.30	0.91	0.99	1.19	0.58	1.22

Transducer Model:L12~5-128L40-BEB

Global Maximum Output Levels	Mode of operation						
	B	M	B+M	PW	B+PW	B+CF/B+PDI/B+DPDI	B+CF+PW/B+PDI+PW/B+DPDI+PW
Max $I_{SPTA.3(mW/cm^2)}$	52.72	78.96	126.16	598.00	644.07	122.65	715.71
Min $I_{SPTA.3(mW/cm^2)}$	13.18	19.74	31.54	179.50	161.02	30.66	178.93
Max MI	1.56	1.56	1.56	1.26	1.56	1.56	1.56
Min MI	0.39	0.39	0.39	0.32	0.39	0.39	0.39
Max TIS	0.55	0.07	0.57	0.43	0.89	0.53	0.95
Min TIS	0.14	0.2	0.14	0.11	0.22	0.13	0.24
Max TIB	0.55	0.23	0.73	2.22	2.69	0.53	2.73
Max TIB	0.14	0.06	0.18	0.55	0.67	0.13	0.68

## 5. Identification of Predicate Device(s)

Predicate Device :

510(k) Number: K213862

510(k) Summary

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Product Name: HD60 Series Ultrasound Diagnostic System

Manufacturer: Qingdao Hisense Medical Equipment 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 60601-1:2020, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance
- b. IEC 60601-1-2:2014+AMD1:2020 CSV Consolidated version, 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+AMD1:2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- d. IIEC 62359:2010/AMD1:2017 Amendment 1 - Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields
- 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
- g. IEC 62133-2:2017/AMD1:2021 Amendment 1 - 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
- h. 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.

#### 7. Clinical Test Conclusion

No clinical study is included in this submission.

## 510(k) Summary

## 8. Substantially Equivalent (SE) Comparison

Table 2 Comparison of Technology Characteristics

Item	Proposed Device(s)	Predicate Device(s)	Remark
Device name	Color Doppler Ultrasound Diagnostic System	HD60 Series Ultrasound Diagnostic System	/
Regulation Name	Ultrasonic Pulsed Doppler Imaging System	Ultrasonic Pulsed Doppler Imaging System	SE
Product Code	IYN, IYO, ITX	IYN, IYO, ITX	SE
Regulation Number	892.1560 892.1570 892.1550	892.1560 892.1570 892.1550	SE
<b>Comparison Statement</b>	<b>The proposed device has same classification information as the predicate device.</b>		
Intended Use	<p>The Color Doppler Ultrasound Diagnostic System is a general-purpose ultrasound system. It is intended for use by, or under the direction of a qualified and trained physician for ultrasound imaging, measurement, display and analysis of the human body and fluid. The device is intended for use in a hospital environment.</p> <p>The systems support the following clinical applications: Ultrasound examination and diagnosis of abdomen, obstetrics, gynecology, small organ (Thyroid, Galactophore, Testis) and cardiac. Modes of operation include: 3D Imaging mode, B, M, PW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Combined modes: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.</p>	<p>The HD60 Series Ultrasound Diagnostic System is a general-purpose ultrasound system. It is intended for use by, or under the direction of a qualified and trained physician for ultrasound imaging, measurement, display and analysis of the human body and fluid. The device is intended for use in a hospital environment.</p> <p>The systems support the following clinical applications: The HD60 series Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ, neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac (adult, pediatric), peripheral vessel, and urology exams. Modes of operation include: 3D/4D Imaging mode, B, M, PW Doppler,</p>	Analyse1

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		CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Combined modes: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.	
<b>Comparison Statement</b>	<b>The proposed device has similar intended use as the predicate device.</b>		
<b>Main Unit Technical Specifications</b>			
User	Qualified and trained physician	Qualified and trained physician	/
Environment	Hospital environment	Hospital environment	SE
Design	Autocorrelation for color processing and FFT for pulse Doppler processing. Supporting Linear and convex array probes.	Autocorrelation for color processing and FFT for pulse Doppler processing. Supporting Linear, Curve, Phase array and Volume probes.	SE
Patient Contact Materials	Material meet ISO 10993-1 and FDA guidance	Material meet ISO 10993-1 and FDA guidance	SE
Mode of operation	3D Imaging mode, B, M, PW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Combined modes: B/M, B/Color M, B/PWD, B/Color/ PWD, B/Power/PWD.	3D/4D Imaging mode, B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Combined modes: B/M, B/Color M, B/PWD or CWD, B/Color/ PWD or CWD, B/Power/PWD.	Analyse1
Functions	<ul style="list-style-type: none"> <li>➤ Spatial compound imaging</li> <li>➤ Frequency compound imaging</li> <li>➤ One-Click Optimization Speckle reduction imaging (SRI)</li> <li>➤ PDI (power Doppler imaging), DPDI (directional power Doppler imaging), and TDI (tissue Doppler imaging)</li> <li>➤ Angle deflection of linear array probes</li> <li>➤ High-pulse repetition frequency</li> <li>➤ Puncture guidance and puncture enhancement,</li> </ul>	<ul style="list-style-type: none"> <li>➤ Spatial compound imaging</li> <li>➤ Frequency compound imaging</li> <li>➤ One-Click Optimization Speckle reduction imaging (SRI)</li> <li>➤ PDI (power Doppler imaging), DPDI (directional power Doppler imaging), and TDI (tissue Doppler imaging)</li> <li>➤ Angle deflection of linear array probes</li> <li>➤ High-pulse repetition frequency</li> </ul>	Analyse2

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	<ul style="list-style-type: none"> <li>➤ with real-time double-screen comparison</li> <li>➤ Tissue-specific imaging</li> <li>➤ Extended imaging</li> <li>➤ TVI (Tissue Doppler imaging, TDI)</li> <li>➤ Curve Anatomical M Mode</li> <li>➤ Strain rate imaging</li> <li>➤ High-resolution blood flow</li> <li>➤ Image comparison(dynamic and static images)</li> </ul>	<ul style="list-style-type: none"> <li>➤ Puncture guidance and puncture enhancement,</li> <li>➤ with real-time double-screen comparison</li> <li>➤ Tissue-specific imaging</li> <li>➤ Extended imaging</li> <li>➤ TVI (Tissue Doppler imaging, TDI)</li> <li>➤ Curve Anatomical M Mode</li> <li>➤ Strain rate imaging</li> <li>➤ Elastography (Elasticity imaging)</li> <li>➤ High-resolution blood flow</li> <li>➤ Image comparison(dynamic and static images)</li> <li>➤ DICOM</li> <li>➤ Teaching System</li> <li>➤ ECG</li> </ul>	
Measurements	Basic measurement: Distance, Area,Circumference Volume, Velocity, Time	Basic measurement: Distance, Area,Circumference Volume, Velocity, Time	SE
Transducer Types	Convex array Linear array	Convex array Phased array Linear array Micro convex array Volume	Analyse2
Acoustic Output within FDA guidelines	Track 3; $Ispta.3 \leq 720 \text{ mW/cm}^2$ $MI \leq 1.9$ $TI \leq 6.0$	Track 3; $Ispta.3 \leq 720 \text{ mW/cm}^2$ $MI \leq 1.9$ $TI \leq 6.0$	SE
<b>Comparison Statement:</b>	<b>The proposed device has the similar main unit specifications with the predicate device.</b>		

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<b>Applied Standards:</b>			
general safety and effectiveness information	IEC 60601-1	ANSI/AAMI ES60601-1	Analyse3
	IEC60601-2-37	IEC60601-2-37	SE
	IEC60601-1-2	IEC60601-1-2	SE
	ISO 10993-1	ISO 10993-1	SE
<b>Comparison Statement</b>	<b>The proposed probe has similar applied Standards with the predicate device.</b>		

510(k) Summary

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## 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 intended use, such as proposed device is not applicable for neonatal, and operation mode not include 4D Imaging mode etc. However, the intended use and operation mode range for the proposed device can be covered in the range of predicate device. Therefore, this difference will not affect substantially equivalence between proposed device and equivalent device.

Analyse 2: The device and predicate device have difference in transducer types, such as proposed device is not include phased array and micro convex array, and function is not include Elastography (Elasticity imaging), Teaching System, DICOM, ECG. However, the intended use and operation mode range for the proposed device can be covered in the range of predicate device. Therefore, this difference will not affect substantially equivalence between proposed device and equivalent device.

Analyse 3: The device and predicate device have difference in standard. The predicate device applied ANSI/AAMI ES60601-1. However, the proposed device applied IEC 60601-1 also consistent with FDA recognized consensus standard. Therefore, this difference will not affect substantially equivalence between proposed device and equivalent device.

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