Wuhan United Imaging Healthcare Co.,Ltd
Xin GAO
RA Manager
#99 Gaokeyuan Rd.,East Lake High-Tech Development Zone
Wuhan, Hubei 430206
China

May 15, 2026

Re: K253716
Trade/Device Name: uSONIQUE Genesis, uSONIQUE Genesis Pro, uSONIQUE Genesis Elite, uSONIQUE Genesis Super, uSONIQUE Pulse, uSONIQUE Pulse Pro, uSONIQUE Pulse Elite, uSONIQUE Pulse Super, uSONIQUE Venus, uSONIQUE Venus Pro, uSONIQUE Venus Elite, uSONIQUE Venus Super
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, QIH
Dated: November 21, 2025
Received: November 24, 2025

Dear Xin GAO:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Digitally signed by Michael D. O'hara -S
Date: 2026.05.15 14:47:21 -04'00'

For

Yanna Kang
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253716

Please provide the device trade name(s).

uSONIQUE Genesis, uSONIQUE Genesis Pro, uSONIQUE Genesis Elite, uSONIQUE Genesis Super, uSONIQUE Pulse, uSONIQUE Pulse Pro, uSONIQUE Pulse Elite, uSONIQUE Pulse Super, uSONIQUE Venus, uSONIQUE Venus Pro, uSONIQUE Venus Elite, uSONIQUE Venus Super

Please provide your Indications for Use below.

The Ultrasonic Pulsed Doppler Imaging System is used for ultrasound scanning of the whole body. It is intended for use by qualified and trained healthcare professionals in a hospital or medical clinic to perform ultrasound diagnostic examinations, supporting the following clinical applications: Abdominal (including Renal, Gynecological, and Obstetric), Pediatric, Small Parts, Cranial(Neonatal Cephalic, Adult Cephalic), Cardiac, Peripheral Vascular, Musculoskeletal, Urological.
Modes of operation include: B Mode, M Mode, Color Mode, PW Mode, CW Mode, 3D/4D Mode, Strain Elastography Imaging, Shear Wave Elastography Imaging. Combined modes: B/M, B/Color, B/PW, B/Color/PW.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510 (k) SUMMARY K253716

1. Date of Preparation

May 14, 2026

2. Sponsor Identification

Wuhan United Imaging Healthcare Co.,Ltd.
No.99 Gaokeyuan Road, East Lake High-tech Development Zone 430206 Wuhan P.R.China

Contact Person: Xin GAO
Position: Regulatory Affair Manager
Tel: +86-021-67076888-5386
Fax: +86-021-67076889
Email: xin.gao@united-imaging.com

3. Identification of Proposed Device

Trade/ Device Name:	uSONIQUE Genesis, uSONIQUE Genesis Pro, uSONIQUE Genesis Elite, uSONIQUE Genesis Super, uSONIQUE Pulse, uSONIQUE Pulse Pro, uSONIQUE Pulse Elite, uSONIQUE Pulse Super, uSONIQUE Venus, uSONIQUE Venus Pro, uSONIQUE Venus Elite, uSONIQUE Venus Super
Common Name:	Ultrasonic Pulsed Doppler Imaging System
Model(s):	uSONIQUE Genesis, uSONIQUE Genesis Pro, uSONIQUE Genesis Elite, uSONIQUE Genesis Super, uSONIQUE Pulse, uSONIQUE Pulse Pro, uSONIQUE Pulse Elite, uSONIQUE Pulse Super, uSONIQUE Venus, uSONIQUE Venus Pro, uSONIQUE Venus Elite, uSONIQUE Venus Super

Regulatory Information
Regulation Number: 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: II
Product Code: IYN, IYO, ITX, QIH
Review Panel: Radiology

4. Identification of Primary/Reference Device(s)

Predicate Device

510(k) Number: K231966
Device Name: LOGIQ E10
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: II
Product Code: IYN, IYO, ITX
Review Panel: Radiology

Reference Device#1

510(k) Number: K223830
Device Name: Ultrasound System 2300
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: II
Product Code: IYN, IYO, ITX
Review Panel: Radiology

Reference Device#2

510(k) Number: K200743, K220882
Device Name: Vivid E80, Vivid E90, Vivid E95
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: II
Product Code: IYN, IYO, ITX
Review Panel: Radiology

Reference Device#3

510(k) Number: K231965
Device Name: Voluson Expert 22, Voluson Expert 20, Voluson Expert 18
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: II
Product Code: IYN, IYO, ITX
Review Panel: Radiology

Reference Device#4

510(k) Number: K240850
Device Name: EPIQ Series, Affiniti Series Diagnostic Ultrasound
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: II
Product Code: IYN, IYO, ITX
Review Panel: Radiology

Reference Device#5

510(k) Number: K221300
Device Name: Consona N9, Consonance N9 Pro, Consona N9 Super, Consona Nova, Consona N9S, Consona NI, Consona NT, Nuewa N9, Recho N9, Consona N9 Exp, Consona N9 Elite, Resona N9, Consona N9T, Consona N8, Consona N8 Pro, Consona N8 Super, Consona OR, Consona N8S, Consona OI, Consona OT, Consona N8 Exp, Consona N8 Elite, Consona N8T, Consona N7, Consona N7 Pro, Consona N7 Super, Consona VR, Consona N7S, Consona VI, Consona VT, Consona N7 Exp, Consona N7 Elite, Consona N7T
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: II
Product Code: IYN, IYO, ITX
Review Panel: Radiology

5. Device Description

The Ultrasonic Pulsed Doppler Imaging System is a full featured, track 3, general purpose diagnostic ultrasound system which consists of a mobile console approximately 550 mm wide (23.8-inch monitor) or 622(27-inch monitor), 1040 mm deep and 1225 mm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, control panel, 15.6-inch high resolution touch screen, 23.8-inch high resolution LCD touch monitor or 27-inch OLED ultra-high resolution touch monitor.

6. Indications for Use

The Ultrasonic Pulsed Doppler Imaging System is used for ultrasound scanning of the whole body. It is intended for use by qualified and trained healthcare professionals in a hospital or medical clinic to perform ultrasound diagnostic examinations, supporting

the following clinical applications: Abdominal (including Renal, Gynecological, and Obstetric), Pediatric, Small Parts, Cranial(Neonatal Cephalic, Adult Cephalic), Cardiac, Peripheral Vascular, Musculoskeletal, Urological.
Modes of operation include: B Mode, M Mode, Color Mode, PW Mode, CW Mode, 3D/4D Mode, Strain Elastography Imaging, Shear Wave Elastography Imaging. Combined modes: B/M, B/Color, B/PW, B/Color/PW.

7. Comparison of Technological Characteristics with the Predicate Device

The differences from the predicate device are discussed in the comparison table in this submission as below.

Table 1 Comparison to Predicate Device

ITEM	Proposed Device uSONIQUE Genesis, uSONIQUE Genesis Pro, uSONIQUE Genesis Elite, uSONIQUE Genesis Super	Proposed Device uSONIQUE Pulse, uSONIQUE Pulse Pro, uSONIQUE Pulse Elite, uSONIQUE Pulse Super	Proposed Device uSONIQUE Venus, uSONIQUE Venus Pro, uSONIQUE Venus Elite, uSONIQUE Venus Super	Predicate Device LOGIQ E10 (K231966)	Remark
Design	Those devices transmit ultrasonic energy into patients, perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, as well as calculations.	Those devices transmit ultrasonic energy into patients, perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, as well as calculations.	Those devices transmit ultrasonic energy into patients, perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, as well as calculations.	This device transmits ultrasonic energy into patients, performs post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. It allows for specialized measurements of structures and flow, as well as calculations.	Same
Patient Contact Materials	Material meet ISO 10993-1 and FDA guidance.	Material meet ISO 10993-1 and FDA guidance.	Material meet ISO 10993-1 and FDA guidance.	Material meet ISO 10993-1 and FDA guidance.	Same
Acoustic Output	• Track 3 • Ispta.3 ≤ 720 mW/cm^2	• Track 3 • Ispta.3 ≤ 720 mW/cm^2	• Track 3 • Ispta.3 ≤ 720 mW/cm^2	• Track 3 • Ispta.3 ≤ 720 mW/cm^2	Same

ITEM	Proposed Device uSONIQUE Genesis, uSONIQUE Genesis Pro, uSONIQUE Genesis Elite, uSONIQUE Genesis Super	Proposed Device uSONIQUE Pulse, uSONIQUE Pulse Pro, uSONIQUE Pulse Elite, uSONIQUE Pulse Super	Proposed Device uSONIQUE Venus, uSONIQUE Venus Pro, uSONIQUE Venus Elite, uSONIQUE Venus Super	Predicate Device LOGIQ E10 (K231966)	Remark
	• MI ≤ 1.9 • TI ≤ 6.0	• MI ≤ 1.9 • TI ≤ 6.0	• MI ≤ 1.9 • TI ≤ 6.0	• MI ≤ 1.9 • TI ≤ 6.0	
Probe	• Phased Array: uS5-1, uS9-2, uSC5-1, uS12-4 • Curved Array: uMC7-1, uC9-1, uC10-2, uBC7-1, uE11-2, uMC7-1VN, uBC7-1VN • Linear Array: uML12-2, uML15-3, uL18-6, uL32-8, uHL18-8, uL15-3 • Volume Probes (4D): uVC9-1, uVE10-2 • Pencil Probe: uCW2	• Phased Array: uS5-1, uS9-2, uSC5-1, uS12-4 • Curved Array: uMC7-1, uC9-1, uC10-2, uBC7-1, uE11-2 • Linear Array: uML12-2, uML15-3, uL18-6, uL32-8, uL15-3 • Volume Probes (4D): uVC9-1, uVE10-2 • Pencil Probe: uCW2	• Phased Array: uS5-1, uS9-2, uSC5-1, uS12-4 • Curved Array: uMC7-1, uC9-1, uC10-2, uBC7-1, uE11-2, uMC7-1VN, uBC7-1VN • Linear Array: uML12-2, uML15-3, uL18-6, uL32-8, uL15-3 • Volume Probes (4D): uVC9-1, uVE10-2	• Phased Array • Curved Array • Linear Array • Volume Probes (4D) • Split Crystal (CW)	Note 1
Measurement	Categories include the following: • Abdomen • Obstetrics • Gynecology • Cardiology • Vascular • Urology	Categories include the following: • Abdomen • Obstetrics • Gynecology • Cardiology • Vascular • Urology	Categories include the following: • Abdomen • Obstetrics • Gynecology • Cardiology • Vascular • Urology	Categories include the following: • Abdomen • Obstetrics • Gynecology • Cardiology • Vascular • Urology	Same

ITEM	Proposed Device uSONIQUE Genesis, uSONIQUE Genesis Pro, uSONIQUE Genesis Elite, uSONIQUE Genesis Super	Proposed Device uSONIQUE Pulse, uSONIQUE Pulse Pro, uSONIQUE Pulse Elite, uSONIQUE Pulse Super	Proposed Device uSONIQUE Venus, uSONIQUE Venus Pro, uSONIQUE Venus Elite, uSONIQUE Venus Super	Predicate Device LOGIQ E10 (K231966)	Remark
	• Small Organ • Pediatrics • Musculoskeletal	• Small Organ • Pediatrics • Musculoskeletal	• Small Organ • Pediatrics • Musculoskeletal	• Small Organ • Pediatrics • Musculoskeletal	
Operating Modes	• B Mode • C Mode • PW Mode • CW Mode • M Mode • Tissue Doppler Imaging Mode (TDI Mode) • Tissue Doppler Energy Imaging Mode (TEI Mode) • Pulsed-wave Tissue Doppler Imaging Mode (TDI-PW Mode) • Power Doppler Imaging Mode (PDI Mode)	• B Mode • C Mode • PW Mode • CW Mode • M Mode • Tissue Doppler Imaging Mode (TDI Mode) • Tissue Doppler Energy Imaging Mode (TEI Mode) • Pulsed-wave Tissue Doppler Imaging Mode (TDI-PW Mode) • Power Doppler Imaging Mode (PDI Mode)	• B Mode • C Mode • PW Mode • CW Mode • M Mode • Tissue Doppler Imaging Mode (TDI Mode) • Tissue Doppler Energy Imaging Mode (TEI Mode) • Pulsed-wave Tissue Doppler Imaging Mode (TDI-PW Mode) • Power Doppler Imaging Mode (PDI Mode)	• B Mode • C Mode • PW Mode • CW Mode • M Mode • Tissue Doppler Imaging Mode (TDI Mode) • Tissue Doppler Energy Imaging Mode (TEI Mode) • Pulsed-wave Tissue Doppler Imaging Mode (TDI-PW Mode) • Power Doppler Imaging Mode (PDI Mode)	Same
Labeling	Conforms to 21 CFR Part 801	Conforms to 21 CFR Part 801	Conforms to 21 CFR Part 801	Conforms to 21 CFR Part 801	Same
Advanced Function					
Strain Elastography Imaging (SE)	Yes	Yes	Yes	Strain Elastography	Same
Shear Wave Elastography	Yes	Yes	Yes	Shear Wave Elastography	Same

ITEM	Proposed Device uSONIQUE Genesis, uSONIQUE Genesis Pro, uSONIQUE Genesis Elite, uSONIQUE Genesis Super	Proposed Device uSONIQUE Pulse, uSONIQUE Pulse Pro, uSONIQUE Pulse Elite, uSONIQUE Pulse Super	Proposed Device uSONIQUE Venus, uSONIQUE Venus Pro, uSONIQUE Venus Elite, uSONIQUE Venus Super	Predicate Device LOGIQ E10 (K231966)	Remark
Imaging (SWE)					
Contrast-Enhanced Ultrasound (CEUS)	Yes	Yes	Yes	Contrast Imaging	Same
MicroFlow Imaging (uMFI)	Yes	Yes	Yes	Micro Vascular Imaging (MVI)	Same
3D/4D Mode	Yes	No	Yes	3D/4D	Note 2
Panorama Imaging	Yes	Yes	Yes	Extended Field of View (LOGIQ View)	Same
Stress Echo	Yes	Yes	No	Stress Echo	Note 3
Biopsy Guide	Yes	Yes	Yes	Biopsy Guide	Same
Needle Enhancement (uNeedle)	Yes	Yes	Yes	BSteer+	Same
Fusion Navigation	Yes	No	Yes	Volume Navigation	Note 4
Auto OB	Yes	Yes	Yes	OB Measure Assistant	Note 5
Auto EF	Yes	Yes	Yes	Auto EF2.0	Note 6
Fast EF	Yes	Yes	Yes	Auto EF2.0	
TDIQ (Tissue Doppler Imaging Quantitative Analysis)	Yes	Yes	Yes	Q Analysis	Same

Table 2 Comparison to Reference Device#1

ITEM	Proposed Device uSONIQUE Genesis, uSONIQUE Genesis Pro, uSONIQUE Genesis Elite, uSONIQUE Genesis Super	Proposed Device uSONIQUE Pulse, uSONIQUE Pulse Pro, uSONIQUE Pulse Elite, uSONIQUE Pulse Super	Proposed Device uSONIQUE Venus, uSONIQUE Venus Pro, uSONIQUE Venus Elite, uSONIQUE Venus Super	Reference Device#1 Ultrasound System 2300 (K223830)	Remark
Probe	Curved Array (Multiplanar):	No	Curved Array (Multiplanar):	Curved Array (Multiplanar)	Note 7

ITEM	Proposed Device uSONIQUE Genesis, uSONIQUE Genesis Pro, uSONIQUE Genesis Elite, uSONIQUE Genesis Super	Proposed Device uSONIQUE Pulse, uSONIQUE Pulse Pro, uSONIQUE Pulse Elite, uSONIQUE Pulse Super	Proposed Device uSONIQUE Venus, uSONIQUE Venus Pro, uSONIQUE Venus Elite, uSONIQUE Venus Super	Reference Device#1 Ultrasound System 2300 (K223830)	Remark
	uCL14-3, uCCL14-3, uCCL14-3VN		uCL14-3, uCCL14-3, uCCL14-3VN		

Table 3 Comparison to Reference Device#2

ITEM	Proposed Device uSONIQUE Genesis, uSONIQUE Genesis Pro, uSONIQUE Genesis Elite, uSONIQUE Genesis Super	Proposed Device uSONIQUE Pulse, uSONIQUE Pulse Pro, uSONIQUE Pulse Elite, uSONIQUE Pulse Super	Proposed Device uSONIQUE Venus, uSONIQUE Venus Pro, uSONIQUE Venus Elite, uSONIQUE Venus Super	Reference Device#2 Vivid E80/ Vivid E90/ Vivid E95(K200743, K220882)	Remark
Probe	TEE Probe: uXT7-2, uXT8-2	TEE Probe: uXT7-2, uXT8-2	No	TEE Probe	Note 8
Advanced Function					
4D TEE Imaging	Yes	Yes	No	3D(4D) TEE imaging	Note 9
4D MVQ (4D Mitral Valve Quantification)	Yes	Yes	No	4D Auto MVQ(K220882)	
Fast Strain	Yes	Yes	Yes	AFI(K200743)	Note 10
2D Strain LV (2D Strain Left Ventricle)	Yes	Yes	Yes	AFI(K200743)	Same
2D Strain RV (2D Strain Right Ventricle)	Yes	Yes	Yes	AFI RV(K200743)	Same
2D Strain LA (2D Strain Left Atrium)	Yes	Yes	Yes	AFI LA(K200743)	Same
4D LAAQ (4D Left Atrial Appendage	Yes	Yes	No	4D Auto LAQ(K220882)	Note 11

ITEM	Proposed Device uSONIQUE Genesis, uSONIQUE Genesis Pro, uSONIQUE Genesis Elite, uSONIQUE Genesis Super	Proposed Device uSONIQUE Pulse, uSONIQUE Pulse Pro, uSONIQUE Pulse Elite, uSONIQUE Pulse Super	Proposed Device uSONIQUE Venus, uSONIQUE Venus Pro, uSONIQUE Venus Elite, uSONIQUE Venus Super	Reference Device#2 Vivid E80/ Vivid E90/ Vivid E95(K200743, K220882)	Remark
Quantification)					

Table 4 Comparison to Reference Device#3

ITEM	Proposed Device uSONIQUE Genesis, uSONIQUE Genesis Pro, uSONIQUE Genesis Elite, uSONIQUE Genesis Super	Proposed Device uSONIQUE Pulse, uSONIQUE Pulse Pro, uSONIQUE Pulse Elite, uSONIQUE Pulse Super	Proposed Device uSONIQUE Venus, uSONIQUE Venus Pro, uSONIQUE Venus Elite, uSONIQUE Venus Super	Reference Device#3 Voluson Expert 22/ Voluson Expert 20/ Voluson Expert 18 (K231965)	Remark
Auto Workflow(uWorks ABD, uWorks Echo, uWorks OB)	Yes	Yes	Yes	SonoLyst	Note 12

Table 5 Comparison to Reference Device #4

ITEM	Proposed Device uSONIQUE Genesis, uSONIQUE Genesis Pro, uSONIQUE Genesis Elite, uSONIQUE Genesis Super	Proposed Device uSONIQUE Pulse, uSONIQUE Pulse Pro, uSONIQUE Pulse Elite, uSONIQUE Pulse Super	Proposed Device uSONIQUE Venus, uSONIQUE Venus Pro, uSONIQUE Venus Elite, uSONIQUE Venus Super	Reference Device 4 EPIQ Series Diagnostic Ultrasound System; Affiniti Series Diagnostic Ultrasound System (K240850)	Remark
Auto WMA (Auto Wall Motion Analysis)	Yes	Yes	Yes	Auto SWMS	Same

Table 6 Comparison to Reference Device# 5

ITEM	Proposed Device uSONIQUE Genesis, uSONIQUE Genesis Pro, uSONIQUE Genesis Elite, uSONIQUE Genesis Super	Proposed Device uSONIQUE Pulse, uSONIQUE Pulse Pro, uSONIQUE Pulse Elite, uSONIQUE Pulse Super	Proposed Device uSONIQUE Venus, uSONIQUE Venus Pro, uSONIQUE Venus Elite, uSONIQUE Venus Super	Reference Device 5 Consona Series(K221300)	Remark
Auto HRI (Auto Hepato-Renal Index Measurement)	Yes	Yes	Yes	Smart HRI	Same
Auto Bladder (Auto Bladder Volume Measurement)	Yes	Yes	Yes	Smart Bladder	Same
Auto Fetal HR (Auto Fetal HR Measurement)	Yes	Yes	Yes	Smart Fetal HR	Same
Auto IVC (Auto Inferior Vena Cava Measurement)	Yes	Yes	Yes	Smart IVC	Same
Auto Hip (Auto Hip Measurement)	Yes	Yes	Yes	Smart Hip	Same
Auto IMT (Auto Intima-Media Thickness Measurement)	Yes	Yes	Yes	IMT	Same
Auto ICV (Auto Intracranial Volume Measurement)	Yes	No	Yes	Smart ICV	Note 13
Auto NT (Auto Nuchal Translucency Measurement)	Yes	No	Yes	Smart NT	
Auto CNS (Auto Fetal Central Nervous System analysis)	Yes	No	Yes	Smart Planes CNS	
Auto FLC (Auto Follicle Measurement)	Yes	No	Yes	Smart FLC	
Auto Pelvic (Auto Pelvic Measurement)	Yes	No	Yes	Smart Pelvic	
Auto Endo (Auto Endometrial Measurement)	Yes	No	Yes	Smart Volume(3D) Smart Scene(2D)	Note 14

Justification	
Note 1	Compared to the predicate device, the probe types are the same. The probe scope of uSONIQUE Genesis, uSONIQUE Pulse and uSONIQUE Venus series products is different. Among them, the uSONIQUE Genesis series products offer the most comprehensive range of probe types. Whereas the uSONIQUE Pulse series does not include uHL18-8, uMC7-1VN, uBC7-1VN. The uSONIQUE Venus series does not include uHL18-8, uCW2. The difference did not raise new safety and effectiveness concerns.
Note 2	uSONIQUE Pulse series do not support 3D/4D Mode. The difference did not raise new safety and effectiveness concerns.
Note 3	uSONIQUE Venus series do not support Stress Echo. The difference did not raise new safety and effectiveness concerns.
Note 4	uSONIQUE Pulse series do not support Fusion Navigation. The difference did not raise new safety and effectiveness concerns.
Note 5	The proposed devices and predicate device all support Auto OB. The only difference is that Auto OB in the proposed device adopt deep learning technology. Performance evaluation were conducted on the proposed devices. It is shown that the difference did not raise new safety and effectiveness concerns.
Note 6	For the proposed device, ejection fraction (EF) measurement is separated into two distinct functional modes based on workflow: non-real-time and real-time scenarios, corresponding to “Auto EF” and “Fast EF,” respectively. In contrast, the predicate device does not differentiate between these scenarios and provides a single EF measurement function. Performance evaluation were conducted on the proposed devices. It is shown that the difference did not raise new safety and effectiveness concerns.
Note 7	Compared to the predicate device, the probe types are the same and uSONIQUE Pulse series do not include uCL14-3, uCCL14-3, uCCL14-3VN. The difference did not raise new safety and effectiveness concerns.
Note 8	Compared to the reference device, the probe types are the same and uSONIQUE Venus series do not include uXT7-2, uXT8-2. The difference did not raise new safety and effectiveness concerns.
Note 9	uSONIQUE Venus series do not support 4D TEE imaging. The difference did not raise new safety and effectiveness concerns.
Note 10	For the proposed device, 2D Strain(AFI) measurement is divided into two distinct functional modes based on workflow: non-real-time and real-time scenarios, corresponding to “2D Strain” and “Fast Strain,” respectively. In contrast, the predicate device is used primarily in non-real-time scenarios. Performance evaluation was conducted on the proposed device, and the results showed that this difference does not raise new safety or effectiveness concerns.
Note 11	uSONIQUE Venus series do not support 4D LAAQ. The difference did not raise new safety and effectiveness concerns.
Note 12	The proposed devices and reference device all support auto workflow. The difference is that auto workflow included in the reference device is only applicable to obstetrics and auto workflow included in the proposed devices is applicable to abdomen, cardiology and obstetrics. Performance evaluation were conducted on the proposed devices. It is shown that the difference did not raise new safety and effectiveness concerns.
Note 13	uSONIQUE Pulse series do not support Auto ICV\Auto CNS\ Auto NT\Auto FLC\Auto Pelvic. The difference did not raise new safety and effectiveness concerns.
Note 14	The proposed system includes two endometrial measurement features: Auto Endo and Auto Endo 3D. Among them, Auto Endo corresponds to the Smart Scene feature of the reference device, both supporting 2D endometrial measurement. Auto Endo 3D aligns with the Smart Volume feature of the reference device, both designed for 3D endometrial measurement.uSONIQUE Pulse series do not support Auto Endo. The difference did not raise new safety and effectiveness concerns.

8. Performance Data

The following testing was conducted on the device and were provided in support of the substantial determination.

Non-Clinical Testing

Non-clinical testing including clinical measurement accuracy, acoustic output and image performance tests were conducted for the proposed device to verify that the proposed device met all design specifications as it is Substantially Equivalent (SE) to the predicate device.

UNITED IMAGING HEALTHCARE claims conformance to the following standards and guidance:

Electrical Safety and Electromagnetic Compatibility (EMC)

- ANSI/AAMIES60601-1: 2005/ (R) 2012+A1:2012+C1:2009/(R)2012+A2:2010/(R)2012) [IncludingAmendment2(2021)]Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+A1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-6:2010+A1:2013+A2:2020, Edition 3.2, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
- IEC 62304:2006+AMD1:2015 CSV Consolidated version, Medical device software - Software life cycle processes
- 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
- IEC 60601-2-37:2024, Medical electrical equipment -Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
- IEC 62359:2017, Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields

Software

- NEMA PS 3.1-3.2024(e): Digital Imaging and Communications in Medicine (DICOM)
- Content of Premarket Submissions for Device Software Functions
- Cybersecurity in Medical Devices: Quality System Considerations and Content

of Premarket Submissions

Biocompatibility

- ISO 10993-5: 2009, Edition 3.0, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10: 2021, Edition 4.0, Biological evaluation of medical devices - Part 10: Tests for skin sensitization.
- ISO 10993-23: 2021, Edition 1.0, Biological evaluation of medical devices - Part 23: Tests for irritation.
- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

Other Standards and Guidance

- ISO 14971: 2019, Edition 3.0, Medical Devices – Application of risk management to medical devices
- Code of Federal Regulations, Title 21, Part 820 - Quality System Regulation
- Marketing Clearance of Diagnostic Ultrasound Systems and Transducers

Performance Verification

Non-clinical testing was conducted to verify the features described in this premarket submission.

Various testing has been conducted (such as performance testing for SWE, SE, 4D TEE, CEUS, uNeedle, Fusion Navigation, uMFI, Biopsy Guide, Panoramic Imaging, 3D/4D mode, Auto OB, Auto EF, Fast EF, Auto Workflow(uWorks ABD, uWorks Echo, uWorks OB), Auto HRI, Auto Bladder, Auto IMT, Auto IVC, Fast Strain, 2D Strain LV, 2D Strain RV, 2D Strain LA, Auto WMA, 4D MVQ, 4D LAAQ, Auto NT, Auto Fetal HR, Auto ICV, Auto CNS, Auto Endo, Auto FLC, Auto Pelvic and Auto Hip.

Summary of the Machine Learning Algorithm

- ***Auto EF and Fast EF***

Item	Description
Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance	-The overall model performance was evaluated using the Dice score (for segmentation accuracy) and EF relative error (for biometric measurement precision), specifically for AutoEF/FastEF testing. The predefined performance criteria were a Dice score exceeding 80% and a relative measurement error below 5%. -The -validation dataset was compiled from distinct patient cohorts, including 50 cases each for A2C and A4C views, covering multiple subgroups. -The model demonstrated robust performance, meeting and surpassing the predefined criteria across all metrics. The Fast

	EF/Auto EF of EF measurements has average Dice of 92% and average absolute final measure error of 4.4% in A2C,91.7% and 4.2% in A4C.
Information about clinical subgroups and confounders present in the dataset	Performance testing was performed on the following subgroups Age, Gender, Ethnicity/Country, BMI for two view A2C, A4C. Each view contains 50 test cases: about 30 from Chinese subjects (drawn from 47 subjects) and about 20 from North American subjects (drawn from 27 subjects). The exact counts of Chinese and North American cases vary slightly across views, while the underlying subject pools remain fixed. The subgroup distribution of these 74 subjects is as follows: ● Age: 18-77 years old, >= 10 & <30 years old (17.6%) >= 30 & <50 years old (31.1%) >= 50 & <70 years old (44.6%) >= 70 & <90 years old (6.8%) ● Gender: Female (47.3%); Male (52.7%); ● Ethnicity/Country: China (63.5%); US (36.5%); ● BMI: 15.0-34.75 <18.5 (2.7%) >=18.5 & <24 (24.3%) >=24 & <28 (44.6%) >=28(28.4%)
Information about equipment and protocols used to collect images	The dataset used for final verification was prospectively collected from 30 demographically diverse patients in China and 20 in the USA, using exclusively the Fast EF/Auto EF Measure Assistant function of the Ultrasonic Pulsed Doppler Imaging System (uSONIQUE Genesis). During acquisition, the clinician must follow the sequence provided by the scanning assistant. Upon locating the target view, the probe should be held steady for approximately two seconds to record a 3–5 second cine loop, which must contain at least three full cardiac cycles. Additionally, all data must be anonymized, excluding any personally identifiable information such as patient names or national identification numbers.
Information about how the reference standard was derived from the dataset (i.e. the “truthing” process)	The dataset of 50 patients in the validation set was loaded into the Ultrasonic Pulsed Doppler Imaging System, and the measurement results were generated by the device's automatic measurement function: - Throughout the dataset annotation process, annotators with more than one year of experience are required to label view categories, quality scores(A: High-quality images, B: Low-quality images), anatomical structures, and measurement items. - The annotations were subsequently reviewed for validity by two radiologists (⩾3 years of experience) - Any discrepancies between the reviewers were resolved through ultimate arbitration by a senior radiologist (⩾5 years of experience)
Description of how independence of test data from training data was ensured	The verification data was acquired independently during validation process after the development of the algorithm as described above.

- ***Auto OB***

<table>
<tr><th>Item</th><th>Description</th></tr>
<tr><td>Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance</td><td>- The overall model performance, evaluated using the Dice score for segmentation accuracy and the relative error for biometric measurements, was assessed for the automated quantification of Auto BPD&HC, Auto AC, and Auto HL&FL.

➢ Dice score (Segmentation Accuracy): ≥ 90%;

➢ Relative measurement error: ≤ 5%;

- The validation datasets were compiled from distinct patient cohorts for each measurement type: 7 patients for BPD&HC, 15 patients for AC, and 16 patients for HL&FL.

- The model demonstrated robust performance, meeting and surpassing the predefined criteria across all metrics.

➢ The HC&BPD algorithm achieved an average Dice score of 94.39% and an average relative measurement error of 0.94%.

➢ The AC algorithm, the average Dice score was 96.36%, with an average relative measurement error of 2.63%.

➢ The HL&FL algorithm yielded an average Dice score of 92.73% and an average relative measurement error of 2.16%.</td></tr>
<tr><td>Information about clinical subgroups and confounders present in the dataset</td><td>Performance testing was performed on the following subgroups: Age, Gender, Ethnicity/Country, BMI, and Pregnancy weeks for each view BPD&HC, AC and HL&FL. The total test set consists of 17 cases, where BPD&HC contains 7 test cases, AC contains 15 test cases, and HL&FL contains 16 test cases, all from North American subjects. The subgroup distribution of these 17 subjects is as follows:
● Age: 27-38 years old
● Gender: Female(100%)
● Ethnicity/Country: US (100%);
● BMI: 17-36
<18.5 (12%)
>=18.5 & <=25 (29%)
>25 (59%)
● Pregnancy weeks:
20-24 weeks (76%)
24-38 weeks (24%)</td></tr>
<tr><td>Information about equipment and protocols used to collect images</td><td>The requirements for data acquisition equipment are as follows:
<table>
<tr><th>Manufacturer</th><th>Model</th><th>Collection Settings</th></tr>
<tr><td>GE</td><td>Voluson E8</td><td>Frame rate range is 25-50
Dynamic range is 4-8</td></tr>
</table></td></tr>
</table>

		probe: C2-9	Depth range is 8cm-12cm Gain range is 0-5 Acquisition is single-frame image Acquire transverse section at the level of the thalamus, transverse section of abdominal circumference, long-axis section of the humerus, long-axis section of the femur.
	Samsung	WS80A probe: CA1-7A	Frame rate range is 25-50 Dynamic range is 80-120 Depth range is 8 cm to 12 cm Gain range is 40 to 70 Acquire as a single-frame image Acquire transverse section at thalamic level, transverse section of abdominal circumference, long-axis section of humerus, long-axis section of femur.
	Mindray	Resona 7 probe: SC5-1U	Frame rate range is 25-50 Dynamic range is 100-140 Depth range is 8cm-12cm Gain range is 60-90 Acquisition is single-frame image Acquire transverse section at the level of the thalamus, transverse section of abdominal circumference, long-axis section of the humerus, long-axis section of the femur.
	UIH	Usonique probe: uVC9-1 uMC7-2	Frame rate range is 25-50 Dynamic range is 50-70 Depth range is 8cm-12cm Gain range is 0-15 Acquisition is single-frame image Acquire transverse section at the level of the thalamus, transverse section of abdominal circumference, long-axis section of the humerus, long-axis section of the femur.
	The dataset used for final verification was prospectively collected from demographically diverse patients in the USA, using exclusively the Auto OB Measure Assistant function of		

	the Ultrasonic Pulsed Doppler Imaging System, uSONIQUE Venus.
Information about how the reference standard was derived from the dataset (i.e. the "truthing" process)	To ensure the reliability and accuracy of the reference standard, a rigorous multi-step annotation and validation process was implemented: - Data Pre-processing: Prior to annotation, all patient metadata and device-displayed information were removed. The process was performed solely on raw Ultrasound B-mode images to prevent bias. - Annotation Personnel and Workflow: Annotators with >1 year of experience performed the initial labeling of view categories and anatomical structures on static B-mode images. These annotations were subsequently reviewed for validity by two board-certified radiologists, each with ≥3 years of experience. - Annotation Criteria: Gold standard segmentation masks were required to strictly conform to structural edges and maintain smoothness. For fetal growth parameters—specifically Head Circumference (HC), Biparietal Diameter (BPD), Abdominal Circumference (AC), Humerus Length (HL), and Femur Length (FL)—the start and end points of the measurement lines were verified for anatomical accuracy. - Discrepancy Resolution: Any disagreements between reviewers were resolved through ultimate arbitration by a senior radiologist with ≥5 years of experience. The finalized dataset served as the "Ground Truth." - Performance Assessment: The Auto OB algorithm outputs were compared against the established ground truth. Specifically, the Dice score for segmentation and the Relative Measurement Error for measurements were calculated to thoroughly assess the algorithm's effectiveness across subgroups.
Description of how independence of test data from training data was ensured	To ensure the integrity of the performance evaluation, the test datasets were strictly segregated from the training dataset. We confirm that these datasets are mutually exclusive, with no patient or image overlap between the development and evaluation phases.

- ***uWorks Abd***

Item	**Description**
Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance	- The uWorks Abd algorithm consists of three algorithmic components: view recognition algorithm, quality assessment algorithm and automatic measurement algorithm. - The total average runtime of the three algorithms is projected to within 500ms. -The expected accuracy of view recognition is projected to exceed 90%. -The expected accuracy of quality assessment is projected to exceed 80%.

<table>
<tr><td></td><td>-The expected accuracy of automatic measurement is projected to exceed 80%. The expected error of automatic measurement is projected to below 10%.
- Summary of Results:
The total average runtime of the three algorithms is 63ms.
The view recognition algorithm has average accuracy of 93.94%.
The quality assessment algorithm has average accuracy of 98.04%.
The automatic measure algorithm has average Dice of 90.70% and average measurement error of 8.44%.</td></tr>
<tr><td>Information about clinical subgroups and confounders present in the dataset</td><td>Performance testing was performed on the following subgroups Age, Gender, Ethnicity/Country, BMI for each view of defined 23 views (LL-AA, LL-IVC, PV-LS, SHH, RL-MOD, RL-MT, FHH, PV-RP, GB-LS, GB-TS, CBD, L-RK, RK-LA, RK-SA, PB-TS, PT-TS, PH-TS, PH-LS, LK-LA, LK-SA, SP-LA, BL-TS, BL-LS). Each view contains 55 test cases: about 30 from Chinese subjects (drawn from 201 subjects) and about 25 from North American subjects (drawn from 41 subjects). The exact counts of Chinese and North American cases vary slightly across views, while the underlying subject pools remain fixed. The subgroup distribution of these 242 subjects is as follows:
● Age: 13-77 years old,
< 30 years old (45.04%)
30~50 years old (19.42%)
>50 years old (35.54%)
● Gender: Female (71.90%); Male (28.10%);
● Ethnicity/Country: China (83.06%); US (16.94%);
● BMI: 15.0-36.53
<18.5 (11.16%)
18.5~24.9 (64.88%)
>24.9 (23.97%)</td></tr>
<tr><td>Information about equipment and protocols used to collect images</td><td>The requirements for data acquisition equipment are as follows:
<table>
<tr><td>Equipment manufacturer</td><td>Model / Specification</td><td>Imaging Parameters</td></tr>
<tr><td>UIH</td><td>Model: uSONIQUE Genesis
Probe: uMC7-1</td><td>Frequency: 2~4MHz
Gain: -7 to 7
Depth: 15-20cm
Dynamic range: 62-72
Collection duration: Retrospective storage does not exceed 30s, and prospective storage does not exceed 15s</td></tr>
</table></td></tr>
</table>

	It's required that every case in the test dataset contains the complete set of 23 standard abdomen views. During the acquisition process, the clinician should follow the sequence provided by the scanning assistant. Upon locating the target view, the probe is to be maintained in a stable position for approximately two seconds to save cine loop. Furthermore, all cases must be anonymized, with the exclusion of any personally identifiable information such as the subject's name or national identification number.
Information about how the reference standard was derived from the dataset (i.e. the "truthing" process)	- For each DICOM dataset, radiologist selects 1 to 4 representative frames for annotation. The annotations include: view type, quality score, segmentation masks of key anatomical structures, and relevant clinical measurements. -The annotation scheme will be determined by algorithm engineers, reviewers, and arbitrators, where the reviewers and arbitrators are clinical personnel. After the annotation scheme is finalized, annotators are trained and a pilot annotation process is conducted. The pilot results are fed back to the algorithm engineers, reviewers, and arbitrators to evaluate whether the current annotation quality meets the standard. If not, retraining and communication are carried out until the target annotation quality is achieved. After the trial labeling is qualified, formal data annotation can begin. After each data item is annotated, two reviewers will review the annotation. If both reviewers approve, the annotation for that data item ends. If both reject it, the data must be relabeled or revised. If the two reviewers disagree, an arbitrator must make a decision. If the arbitrator deems the data qualified, the annotation ends; otherwise, relabeling or revision is required. -The entire process referred to the patient's ultrasound imaging data and pathological report (if available).
Description of how independence of test data from training data was ensured	-For the 400 cases of data from China, 280 cases were selected as the training set, 90 cases as the tuning set, and 30 cases as the test set, which are mutually independent; in addition, all 25 cases of data from North America were used as the test set.Therefore, it ensures that the test data is independent of the training data

- ***uWorks Echo***

Item	**Description**
Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance	- The uWorks Echo algorithm primarily consists of three algorithmic components: view recognition algorithm, quality assessment algorithm and automatic measurement algorithm. -The expected accuracy of view recognition is projected to exceed 90%. -The expected accuracy of quality assessment is projected to exceed 80%.

<table>
<tr><td></td><td>-The expected accuracy of automatic measurement is projected to exceed 80%.
- Summary of Results:
The view recognition algorithm has average accuracy of 0.9934.
The quality assessment algorithm has average accuracy of 0.9362.
The automatic measure algorithm has average Dice of 0.9353 and average measurement error of 0.0514.</td></tr>
<tr><td>Information about clinical subgroups and confounders present in the dataset</td><td>Performance testing was performed on the following subgroups Age, Gender, Ethnicity/Country, BMI for each view PLAX, PSAX_AV, PSAX_PA, PSAX_MV, PSAX_PM, PSAX_A, A2C, A3C, A4C, A5C, RVI, S4C, SIVC and SSN. Each view contains 55 test cases: about 30 from Chinese subjects (drawn from 74 subjects) and about 25 from North American subjects (drawn from 37 subjects). The exact counts of Chinese and North American cases vary slightly across views, while the underlying subject pools remain fixed. The subgroup distribution of these 111 subjects is as follows:
● Age: 18-79 years old,
< 40 years old (30%)
>= 40 & <60 years old (36%)
>= 60 years old (34%)
● Gender: Female (44%); Male (56%);
● Ethnicity/Country: China (67%); US (33%);
● BMI: 15.0-36.53
<18.5 (6%)
>=18.5 & <25 (37%)
>=25 (57%)</td></tr>
<tr><td>Information about equipment and protocols used to collect images</td><td>The requirements for data acquisition equipment are as follows:
<table>
<tr><th>Equipment manufacturer</th><th>Model / Specification</th><th>Imaging Parameters</th></tr>
<tr><td>UIH</td><td>Model:
uSONIQUE Genesis
Probe:
uS5-1
uSC5-1</td><td>Frequency Range: 50-70 Hz
Dynamic Range: 10-20 dB
Depth Range: 15-20 cm
Gain Range: 0-20 dB
Sample Acquisition: Dynamic video (3-5 seconds)</td></tr>
</table>
The dataset was consisted of 55 patients collected on the uSONIQUE Genesis corresponding to the cardiac views in US and China. It's required that every case in the test dataset contains the complete set of 14 standard echocardiographic views, which are PLAX, PSAX_AV, PSAX_PA, PSAX_MV, PSAX_PM, PSAX_A, A2C, A3C, A4C, A5C, RVI, S4C, SIVC and SSN. During the acquisition process, the clinician should follow the sequence provided by the</td></tr>
</table>

	scanning assistant. Upon locating the target view, the probe is to be maintained in a stable position for approximately two seconds to save a 3 to 5-second cine loop. The cine loop must encompass a minimum of 3 full cardiac cycles. Furthermore, all cases must be anonymized, with the exclusion of any personally identifiable information such as the subject's name or national identification number.
Information about how the reference standard was derived from the dataset (i.e. the "truthing" process)	- For each case, 1 to 4 frames are selected to evaluate performance metrics for view recognition and quality assessment. These frames are strategically selected to encompass a representative spectrum of image qualities. representative frames for annotation. The annotations include: view type, quality score, segmentation masks of key anatomical structures, and relevant clinical measurements. - Throughout the dataset annotation process, annotators with more than one year of experience are required to label view categories, quality scores (A: High-quality images, B: Low-quality images), anatomical structures, and measurement items. - The annotations were subsequently reviewed for validity by two radiologists (≥3 years of experience) - Any discrepancies between the reviewers were resolved through ultimate arbitration by a senior radiologist (≥5 years of experience)
Description of how independence of test data from training data was ensured	The verification data was acquired independently during validation process after the development of the algorithm as described above.

- ***uWorks OB***

Item	**Description**
Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance	The algorithm of fully automatic obstetric ultrasound workflow function consists of three algorithmic components: view recognition algorithm, quality assessment algorithm and automatic measurement algorithm. -The expected accuracy of view recognition is projected to exceed 90%. -The expected accuracy of quality assessment is projected to exceed 85%. -The expected accuracy of automatic measurement is projected to exceed 80%. -Test Image data were collected from 20 patients. The number of patients available for each specific plane varied: 13 patients for the plane recognition algorithm, 16 patients for the quality assessment algorithm, and 16 patients for the automatic measurement algorithm. - Summary of Results: The view recognition algorithm has average accuracy of 98.94%.

<table>
<tr><td></td><td>The quality assessment algorithm has average accuracy of 90.32%.
The automatic measure algorithm has average Dice of 90.17% and average measurement error of 4.64%.</td></tr>
<tr><td>Information about clinical subgroups and confounders present in the dataset</td><td>Performance testing was performed on the following subgroups: Age, Gender, Ethnicity/Country, and BMI for each view: XS Bilateral Kidneys, 4CH, Sag Ulna And Rad, LVOT, TT, TV, Sag FL, Sag HUM, Sag FLTF, SSL, SSC, Abd Cord Insertion, AC, FMFV, and Coronal Nose And Lips. Each view contains between 5 and 16 test cases, all sourced from a total of 20 North American subjects. The subgroup distribution of these 20 subjects is as follows:
● Age: 22-38 years old (median: 30 years);
● Gender: Female (100%);
● Ethnicity/Country: US (100%);
● BMI: 16-36
<18.5 (20%)
>=18.5 & <25 (30%)
>=25 (50%)</td></tr>
<tr><td>Information about equipment and protocols used to collect images</td><td>The requirements for data acquisition equipment are as follows:
<table>
<tr><th>Equipment Manufacturer</th><th>Model Number and Specifications</th><th>Data Acquisition Settings</th></tr>
<tr><td>UIH-WH</td><td>uSONIQUE Genesis series
probe：
uVC9-1
uMC7-2</td><td>Frame rate range is 25-50 Hz
Dynamic range is 50-70 dB
Depth range is 8cm-12cm
Gain range is 0-15 dB
Sample Acquisition: Dynamic video (3-5 seconds)</td></tr>
</table>
The dataset used for final verification was collected prospectively from demographically diverse patients in the North America and China, exclusively using the Obstetric Scanning Assistant function of the Ultrasonic Pulsed Doppler Imaging System, uSONIQUE Genesis.</td></tr>
<tr><td>Information about how the reference standard was derived from the dataset (i.e. the “truthing” process)</td><td>To ensure the reliability and accuracy of the reference standard, a rigorous multi-step annotation and validation process was implemented:
➢ Data Pre-processing: Prior to annotation, all patient metadata and device-displayed information were removed. The process was performed solely on raw Ultrasound B-mode images to prevent bias.
➢ Annotation Personnel and Workflow: Annotators with >1 year of experience performed the initial labeling of view categories and anatomical structures on static B-mode images. These annotations were subsequently reviewed</td></tr>
</table>

	for validity by two board-certified radiologists, each with ≥3 years of experience. ➢ Annotation Criteria: The annotation content included view type, quality scores, segmentation masks of key anatomical structures (requiring strict adherence to structural edges and smoothness), and relevant clinical measurements. ➢ Discrepancy Resolution: Any disagreements between reviewers were resolved through ultimate arbitration by a senior radiologist with ≥5 years of experience. The finalized dataset served as the "Ground Truth." ➢ Performance Assessment: The output of the uWorks OB algorithm was compared against this Gold Standard. ■ For the view recognition and quality assessment algorithms, accuracy, sensitivity, and specificity were calculated. ■ For the automated measurement algorithms, the Dice score for segmentation and the Relative Measurement Error for measurements were computed to comprehensively evaluate the effectiveness of each algorithm across various subgroups.
Description of how independence of test data from training data was ensured	To ensure the integrity of the performance evaluation, the test datasets were strictly segregated from the training dataset. We confirm that these datasets are mutually exclusive, with no patient or image overlap between the development and evaluation phases.

Summary

The features described in this premarket submission are supported with the results of the testing mentioned above, the proposed device was found to have a safety and effectiveness profile that is similar to the predicate device.

9. Conclusions

Based on the comparison and analysis above, the proposed device has similar indications for use, performance, safety equivalence, and effectiveness as the predicate device. The differences above between the proposed device and predicate device do not affect the intended use, technology characteristics, safety, and effectiveness. And no issues are raised regarding to safety and effectiveness. The proposed device is determined to be Substantially Equivalent (SE) to the predicate device.