510(k) Summary

This Summary of 510(K) Safety and Effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(K) number: **K140364**

1. **Date of submission : January 12, 2014**

2. **Submitter:**
   Chison Medical Imaging Co., Ltd.
   No.8, Xiang Nan Road, Shuo Fang, New District, Wuxi, China 214142

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3. **Proposed Device Identification:**
   Trade/Proprietary: Q Series & i7, i8, i9 Diagnostic Ultrasound System

   Common Name: Diagnostic Ultrasound System with Accessories

   Classification: Regulatory Class: II
   Review Category: Tier II

Classfication Name	21 CFR Section	Product Code
Ultrasonic pulsed doppler imaging system	892.1550	90-IYN
Ultrasonic pulsed echo imaging system	892.1560	90-IYO
Diagnostic ultrasonic transducer	892.1570	90-ITX

4. **Legally Marketed Predicate Device:**
   K101236, GE Voluson E6/E8 /E8 Expert Diagnostic Ultrasound System
   K120801 CHISON iVis60EXPERT, Q6/Q8, i7 Diagnostic Ultrasound Systems

5. **Device Description:**

The Q6/Q8/Q9/Q10/i7/i8 /i9 ultrasound system is an integrated preprogrammed color doppler ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.
The CHISON ultrasound system can be configured either as a portable model (Q6/Q8/Q9/Q10), or as a roll-around model on wheels (i7/i8/i9). These systems are designed with the latest technology, using the same quality procedure as ultrasound systems which have been available in the market for years.

This CHISON ultrasound system is a general purpose, software controlled, diagnostic ultrasound system. Its basic function is to acquire ultrasound echo data and display the image in B-Mode (including Tissue Harmonic Imaging), M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Power Doppler Mode, Directional Power Doppler Mode, TDI Mode or a combination of these modes.3D/4D.

6. Indications for Use:

The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ(breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular, Musculo-skeletal Conventional & Superficial, Transvaginal.

7. Summary of Modifications and Newly Added Features

The Q Series & i7, i8, i9 Diagnostic Ultrasound System employs the same technology as the predicate devices. This submission device is a modification to CHISON iVis60EXPERT,Q6 /Q8, i7 Diagnostic Ultrasound Systems previously cleared in K120801. The submission device also has the same intended uses and basic operating modes as the predicate devices.
The following is a brief overview of the modifications and newly added features. Detailed information is found in Section 1_4 General Device Description of this submission, while Section 1_5 Predicate Device Comparison to Legally Marketed Device includes a discussion of substantial equivalence with the predicate device(s).

Newly added transducers:

D3C60L-B
D3C60L-C
D7L40L-C
D12L40L
D7C10L-C
V6C10L
D5C20L-A
D3C20L
D6C15L-A
D2D16L

V4C40L-C
Newly added software options:
2D Steer
Elastography
Curved Panoramic Imaging
Supper needle
IMT: Auto IMT measurement
vascular measurement package
small parts measurement package
Pediatric measurement package
All of the above modifications have been compared with the predicate devices. The results show that these modifications are substantially equivalent to the predicate devices.

8. Testing:

Laboratory testing was conducted to verify that the 530 system with added transducer met all design specification and was substantially equivalent to the Predicate Device.
The device has been found to conform to applicable medical device safety standards in regards to thermal, mechanical and electrical safety as well as biocompatibility.
IEC 60601-1: 2005 Medical Electrical Equipment - Part 1: General Requirements for Safety
IEC 60601-1-2: 2007 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.
IEC 60601-2-37: 2007 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
NEMA UD 2-2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Version 3.
NEMA UD3: 2004 Standards for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
ISO 10993-1: Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

9. Clinical Test:

No clinical testing was required.

10. Comparison to Predicate Device:

Table 1 Substantial Equivalence Comparison

	Predicate Device		Submission Device	Remark
Product Name (K number)	**Voluson E8/E8Expert K101236**	**CHISON iVis60EXPERT,Q6/Q8,i7 K120801**	**Q Series & i7,i8,i9 TBD**	
Indications for Use	Fetal (Obstetrics); Abdominal (including GYN, pelvic and infertility monitoring/follicle development); Pediatric; Small Organ (breast, testes, thyroid etc); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Musculo-skeletal Conventional and Superficial; Peripheral Vascular ; Transrectal ; Transvaginal and Intraoperative (abdominal, PV and neurological).	Fetal (Obstetrics); Abdomen; Small Organ (Thyroid, testes and breast etc); Cardiac (adult and pediatric); Musculo-skeletal (Conventional and Superficial) ; Peripheral Vascular, Transvaginal, OB/Gyn and Urology.	Fetal (Obstetrics); Abdomen; Pediatric; Small Organ (Thyroid, testes and breast); Cardiac (adult and pediatric); Musculo-skeletal (Conventional and Superficial) ; Peripheral Vascular, Transvaginal, OB/Gyn and Urology.	Same
Design	• Autocorrelation for color processing and FFT for pulse and CW Doppler processing. • Supporting Linear, Curve linear, Phase array and Pencil probes. • Cine play back capability • Image file archive • Software upgrade with USB flash drive. Digital multi-beam forming	• Autocorrelation for color processing, and FFT for pulse and CW Doppler processing. • Supporting Linear, Curve linear, Phase array and Pencil probes. • Cine play back capability • Image file archive • Software upgrade with USB flash drive. • Digital multi-beam forming	• Autocorrelation for color processing and FFT for pulse and CW Doppler processing. • Supporting Linear, Curve linear, Phase array and Pencil probes. • Cine play back capability • Image file archive • Software upgrade with USB flash drive. • Digital multi-beam forming	Same

	Predicate Device		Submission Device	Remark
Product Name (K number)	**Voluson E8/E8Expert K101236**	**CHISON iVis60EXPERT,Q6/Q8,i7 K120801**	**Q Series & i7,i8,i9 TBD**	
Operating Controls	TGC 8 slider	TGC 8 slider	TGC 8 slider	Same
	Depth Range: 0 to 30 cm	Depth Range:0~30cm	Depth Range:0~30cm	Same
	256 shades of gray	256 shades of gray	256 shades of gray	Same
	Image Reverse: Right/Left	Image Reverse: Right/Left	B orientation flip: L/R ,U/D	SE Analysis1
	B persistence: 8 steps	B persistence: 7 steps	B persistence:0~7	Same
	Frequency Selection:3 steps	Frequency Selection:5 steps	Frequency Selection:5 steps	SE Analysis1
	PW Sweep Speed:3 Steps	PW Sweep Speed:3 Steps	PW Sweep Speed:3 Steps	Same
	Angle Correction: ± 0-85° , 1° step	Angle Correction: ± 0-72° , 5° step	Angle Correction: ± 0-80° , 5° step	SE Analysis1
	Steered Linear: 0° - 25°	Steered Linear: : 0— 20°	Steered Linear: : -20° — 20°	SE Analysis1
	Spectrum Inversion	Spectrum Inversion	Spectrum Inversion	Same
	Acoustic Power Range:1-100	Acoustic Power Range:1-100	Acoustic Power Range:1-100	Same
	Doppler Auto Trace	Doppler Auto Trace	Doppler Auto Trace	Same
	Color Maps: 8 maps	Color Maps: 8 maps	Color Maps: 9 maps	SE Analysis1
	CFM Spectrum Inversion	CFM Spectrum Inversion	CFM Spectrum Inversion	Same
	PD Color Maps: 8 maps	PD Color Maps: 4 maps	PD Color Maps: 9 maps	SE Analysis1
	Freeze control: Toggling freeze key	Freeze control: Toggling freeze key	Freeze control: Toggling freeze key	Same
	Color ROI setting: trackball and set key to control size and position	Color ROI setting: trackball and set key to control size and position	Color ROI setting: trackball and set key to control size and position	Same

	Predicate Device		Submission Device	Remark
Product Name (K number)	**Voluson E8/E8Expert K101236**	**CHISON iVis60EXPERT,Q6/Q8,i7 K120801**	**Q Series & i7,i8,i9 TBD**	
	Zoom adjustable	Zoom adjustable	Zoom adjustable	Same
	Cine control : play backward ,play continuously	Cine control : play backward ,play continuously	Cine control : play backward ,play continuously	Same
Safety Compliance	IEC60601-1 Medical electrical equipment - Part 1: General requirements for safety IEC60601-1-2 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC60601-2-37 Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for imitation and delayed-type hypersensitivity	IEC60601-1 Medical electrical equipment - Part 1: General requirements for safety IEC60601-1-2 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC60601-2-37 Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for imitation and delayed-type hypersensitivity	IEC60601-1 Medical electrical equipment - Part 1: General requirements for safety IEC60601-1-2 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC60601-2-37 Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for imitation and delayed-type hypersensitivity	Same

	Predicate Device		Submission Device	Remark
Product Name (K number)	**Voluson E8/E8Expert K101236**	**CHISON iVis60EXPERT,Q6/Q8,i7 K120801**	**Q Series & i7,i8,i9 TBD**	
Patient Contact Materials	Bio-compatible	Bio-compatible	Bio-compatible	Same
Scanning Mode	Electronic Sector Electronic Convex Electronic Linear Mechanic Volume Sweep	Electronic Sector Electronic Convex Electronic Linear Mechanic Volume Sweep	Electronic Sector Electronic Convex Electronic Linear Mechanic Volume Sweep	Same
Operation Mode	B, M (Conventional M), PW, CFM (Color Flow Doppler Mode), PD (Power Doppler Mode), TD (Tissue Doppler Mode), B + Power Doppler Mode, B + CFM Doppler Mode, Automatic Tissue Optimization, SRI II (Speckle reduction imaging), Real-time automatic Doppler calculations, Patient information database, Image Archive on hard drive, 2D-ModeM-Mode (conventional M-Mode), AMM (Anatomical M-Mode), PW Doppler Mode, CW Doppler Mode, High PRF Doppler Mode, Color Flow Doppler Mode (CFM), Power Doppler Mode (PD), HD-Flow Doppler Mode (HD-Flow), Tissue Doppler Mode (TD), M-Color Flow Modes, Elastography, Volume Modes (3D/4D)	B, M (Conventional M), PW,CFM (Color Flow Doppler Mode),PD (Power Doppler Mode), TD (Tissue Doppler Mode),B + Power Doppler Mode, B + CFM Doppler Mode, AIO, SRA, Real-time automatic Doppler calculations, Patient information database, Image Archive on hard drive,2D-ModeM-Mode (conventional M-Mode),Free steering M mode, PW Doppler Mode, CW Doppler Mode, High PRF Doppler Mode, Color Flow Doppler Mode (CFM), Power Doppler Mode (PD), Tissue Doppler Mode (TDI),Color M Volume Modes (3D/4D)	B, M (Conventional M), PW,CFM (Color Flow Doppler Mode),PD (Power Doppler Mode), TD (Tissue Doppler Mode),B + Power Doppler Mode, B + CFM Doppler Mode, AIO, SRA, Real-time automatic Doppler calculations, Patient information database, Image Archive on hard drive,2D-ModeM-Mode (conventional M-Mode),Free steering M mode, PW Doppler Mode, CW Doppler Mode, High PRF Doppler Mode, Color Flow Doppler Mode (CFM), Power Doppler Mode (PD), ,Tissue Doppler Mode (TDI),Color M, Elastography, Volume Modes (3D/4D)	Same

	Predicate Device		Submission Device	Remark
Product Name (K number)	**Voluson E8/E8Expert K101236**	**CHISON iVis60EXPERT,Q6/Q8,i7 K120801**	**Q Series & i7,i8,i9 TBD**	
Display Modes	B, B/M, M, Dual mode, Quad mode,2D Steer, CFM, PW,CW, AMM (Anatomical M-Mode),HPRF,TDI, M-Color Flow Modes, Curved Panoramic Imaging , Trapezoidal image, compound, SRI II (Speckle reduction imaging), Elastography, Real time Triplex capability	B, B/M, M, Dual mode, Quad mode,2D Steer, CFM, PW, CW, Free Steering M mode, HPRF, TDI, Color M, Curved Panoramic Imaging , Trapezoidal image, compound, SRA, Real time Triplex capability	B, B/M, M, Dual mode, Quad mode,2D Steer, CFM, PW, CW, Free Steering M mode, HPRF, TDI, Color M, Curved Panoramic Imaging , Trapezoidal image, compound, SRA, Elastography, Real time Triplex capability	Same
Display Annotations	Patient name ;ID; Hospital Name; Time; Date; Probe Name; Application Name; Gray Scale bar; Frame Rate; Elastography mode; TGC curve ;Cine Frame Number; Recorder Status; Measurement Results; Power output% ;Biopsy Guide Line; ECG Line; M-Mode/Freeze Steering-M Mode; Doppler Mode; Color Flow Imaging Modes;3D/4D Mode; Zoom overview image (zoom box position); Logo; Trackball function;	Patient name ;ID; Hospital Name; Date; Time; date; year; Application Name; Gray Scale bar; Frame Rate; Zoom Factor; TGC curve ;Cine Frame Number; Recorder Status; Measurement Results ;Displayed Acoustic Output; Power output% ;Biopsy Guide Line; ECG Line	Patient name ;ID; Hospital Name; Time; Date; Probe Name; Application Name; Gray Scale bar; Frame Rate; Elastography mode; TGC curve ;Cine Frame Number; Recorder Status; Measurement Results; Power output% ;Biopsy Guide Line; ECG Line; M-Mode/Freeze Steering-M Mode; Doppler Mode; Color Flow Imaging Modes;3D/4D Mode; Zoom overview image (zoom box position); Logo; Trackball function;	Same
Display	19" high-resolution LCD monitor	19" LCD high-resolution monitor for i7	19" LCD high-resolution monitor for i7/i8/i9	SE Analysis2

	Predicate Device		Submission Device	Remark
Product Name (K number)	**Voluson E8/E8Expert K101236**	**CHISON iVis60EXPERT,Q6/Q8,i7 K120801**	**Q Series & i7,i8,i9 TBD**	
Monitor		15" LCD high-resolution monitor for iVis 60/iVis 60EXPERT/Q8/Q6	15" LCD high-resolution monitor for Q6/Q8/Q9/ Q10	
Measurements	Distance; Area(Ellipse); Volume; Ratio; Angle; M Distance; M Time; Velocity; HR; Vs; Vd; Vmean; PI;RI; SD; GYN, OB, Vessel, URO, Small Parts, Pediatrics, Carotid, Cardiac and Abdomen package	Distance; Area(Ellipse); Volume; Ratio; Angle; M Distance; M Time; Velocity; HR; Vs; Vd; Vmean; PI;RI; SD; GYN, OB, Vessel, URO, Small Parts, Pediatrics, Carotid, Cardiac and Abdomen package	Distance; Area(Ellipse); Volume; Ratio; Angle; M Distance; M Time; Velocity; HR; Vs; Vd; Vmean; PI;RI; SD; GYN, OB, Vessel, URO, Small Parts, Pediatrics, Carotid, Cardiac and Abdomen package	Same
Transducer Types & Connectors	Convex Array, Micro convex Array, Sector Phased Array, Linear Array, Volume probe, Pencil probe 4 ports.	Convex Array , Linear Array, Sector Phase array ,Volume probe i7: 4 ports iVis 60/iVis 60EXPERT : 3 ports Q8/Q6: 2 ports	Convex Array , Micro convex Array, Linear Array, Sector Phase array ,Volume probe, Pencil probe i7/i8/i9: 4 ports Q10/Q9/Q8/Q6: 2 ports	SE Analysis3
Principle of Operation	Applying high voltage burst to the Piezoelectric material in the transducer and detect the reflected echo to construct the 2D,3D/4D mode, Doppler color, and Doppler spectrum image for diagnostic purpose.	Applying high voltage burst to the Piezoelectric material in the transducer and detect the reflected echo to construct the 2D,3D/4D mode, Doppler color, and Doppler spectrum image for diagnostic purpose.	Applying high voltage burst to the Piezoelectric material in the transducer and detect the reflected echo to construct the 2D,3D/4D mode, Doppler color, and Doppler spectrum image for diagnostic purpose.	Same
Users / Sites	Hospitals, clinics usage	Hospitals, clinics usage	Hospitals, clinics usage	Same
Acoustic Output	Track 3; MI, TIS, TIC, TIB Derated Ispta: $720mW/cm^2$ maximum,	Track 3; MI, TIS, TIC, TIB Derated Ispta: $720mW/cm^2$	Track 3; MI, TIS, TIC, TIB Derated Ispta: $720mW/cm^2$	Same

	Predicate Device		Submission Device	Remark
Product Name (K number)	**Voluson E8/E8Expert K101236**	**CHISON iVis60EXPERT,Q6/Q8,i7 K120801**	**Q Series & i7,i8,i9 TBD**	
	TIS/TIB/TIC:0.1-4.0 Range, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190 W/cm^2 max	maximum, TIS/TIB/TIC:0.1-4.0 Range, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190 W/cm^2 max	maximum, TIS/TIB/TIC:0.1-4.0 Range, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190 W/cm^2 max	
Power Requirements	Power requirements: AC: 220V - 240V; 100V,115V - 130 V Frequenzy: 50 Hz, 60 Hz (± 2%) Operating temperature: 18-30° C; relative humidity 30-80%;Barometric pressure:700 to 1060 hPa	Power requirements: AC :110V- 230V, Frequenzy:50/60Hz Operating temperature: 10-40° C; relative humidity 30-75%;Barometric pressure:700 to 1060 hPa	Power requirements: AC :100V- 240V, Frequenzy:50-60Hz Operating temperature: 10-40° C; relative humidity 30-75%;Barometric pressure:700 to 1060 hPa	SE Analysis4
Peripherals and Accessories	Remote BW Printer, Remote Color Printer, Remote DVR, Footswitch, VGA OUT, Network, USB,S-Video ,DVI-D out, Audio out,RS232	**Q8/Q6**: LAN port, Footswitch ,USB flash mobile drive, VGA output ,S-video, Remote Video Printer, USB Printer, S-Video **i7:** LAN port, Footswitch ,USB flash mobile drive, VGA output ,S-video, Remote Video Printer, USB Printer, S-Video ,		Same

Comparison Analysis

SE Analysis 1
The Operating Controls item of proposed device and the predicate device are with different Image Reverse/Frequency Selection/Angle Correction/Steered Linear/Color Maps/PD Color Maps, but they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

SE Analysis 2
The screen size of the proposed is smaller than that of the E8. This difference is considered to have no effect on effectiveness and safety.

SE Analysis 3
The Transducer Connectors of the proposed is less than that of the E8. This difference is considered to have no effect on effectiveness and safety.

SE Analysis 4
The Power Supply of the proposed device and the predicate device are AC: 100V- 240V and AC: 220V - 240V; 100V, 115V - 130 V respectively, but both of them comply with IEC60601-1 and IEC 60601-1-2. Therefore, power supply can be considered Substantially Equivalent in safety and effectiveness.

Discussion of Substantially Equivalent

The subject device has same intended use, same product design, same performance effectiveness, and performance safety as the predicate device. The differences above between the subject device and predicate device do not affect the basic design principle, usage, effectiveness and safety of the subject device.

11. Substantially Equivalent Conclusion:

I n accordance with the Federal Food Drug and Cosmetic Act. 21 CFR Part 807 and based on the information provided in this premarket notification, Chison Medical Imaging Co., Ltd. concludes that the CHISON Q Series and i7, i8, i9 Diagnostic Ultrasound System is substantially equivalent to predicate devices with regard to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 2, 2014

Chison Medical Imaging Co., Ltd.
% Mr. Bob Leiker
Leiker Regulatory & Quality
7263 Cronin Circle
DUBLIN CA 94568

Re: K140364
Trade/Device Name: Q Series & i7, i8, i9 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: April 15, 2014
Received: April 18, 2014

Dear Mr. Leiker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Q Series & i7, i8, i9 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

D3C60L, Convex Array
D3C60L-C, Convex Array
D7L40L-C, Linear Array
D12L40L, Linear Array
D6C12L, Micro Convex Array
D7C10L-C, Micro Convex Array
D5C20L, Micro Convex Array
D3C20L, Micro Convex Array
D6C15L-A, Micro Convex Array
D3C60L-B, Convex Array
D7L40L, Linear Array
D7L60L, Linear Array
D7L30L, Linear Array
D7C10L, Micro Convex Array
V6C10L, Volume Probe
D5C20L-A, Micro Convex Array
D6C15L, Micro Convex Array
D3P64L, Phased Array

D6P64L, Phased Array
V4C40L, Volume probe

D2D16L, Pencil Array
V4C40L-C, Volume Probe

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K140364

Device Name

Q Series & i7, i8, i9 Diagnostic Ultrasound Systems

Indications for Use *(Describe)*

The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Cardiac (adult & pediatric); Peripheral Vascular, Musculo-skeletal Conventional & Superficial, Transvaginal.

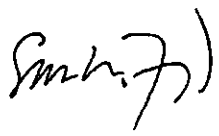
Type of Use *(Select one or both, as applicable)*

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

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



Diagnostic Ultrasound Indications For Use

System: Q6/Q8/Q9/Q10, i7/i8/i9 Diagnostic Ultrasound Systems

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	P	3,5
	Abdominal	P	P	P		P	P	P	P	3,4,5
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	P	P	P		P	P	P	P	4,5
	Small Organ[2] (Specify)	P	P	P		P	P	P	P	4,5
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal	P	P	P		P	P	P	P	3,4,5
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	P	4,5
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	P	4,5
	Other (Urology)	P	P	P		P	P	P	P	4,5
	Other (Ob/GYN)	P	P	P		P	P	P	P	5
Cardiac	Cardiac Adult	P	P	P	P	P	P	P	P	5
	Cardiac Pediatric	P	P	P	P	P	P	P	P	5
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P	P	5

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

Note :1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD,B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy (Super needle)

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____

System: Q6/Q8/Q9/Q10, i7/i8/i9 Diagnostic Ultrasound Systems
Transducer: D3C60L, Convex Array

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	P	5
	Abdominal	P	P	P		P	P	P	P	4,5
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1][2](Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)	P	P	P		P	P	P	P	4,5
	Other (Ob/GYN)	P	P	P		P	P	P	P	5
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel									

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

Note :1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD,B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____

System: Q6/Q8/Q9/Q10, i7/i8/i9 Diagnostic Ultrasound Systems
Transducer: D3C60L-B, Convex Array

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	N	5
	Abdominal	N	N	N		N	N	N	N	4.5
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1][2] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)	N	N	N		N	N	N	N	4.5
	Other (Ob/GYN)	N	N	N		N	N	N	N	5
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel									

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

Note :1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD,B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy

Predicate transducer (K number): K101236, K120801

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____

System: Q6/Q8/Q9/Q10, i7/i8/i9 Diagnostic Ultrasound Systems
Transducer: D3C60L-C, Convex Array

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	N	5
	Abdominal	N	N	N		N	N	N	N	4,5
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)	N	N	N		N	N	N	N	4,5
	Other (Ob/GYN)	N	N	N		N	N	N	N	5
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel									

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

Note :1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD,B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy

Predicate transducer (K number): K101236, K120801

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____

System: Q6/Q8/Q9/Q10, i7/i8/i9 Diagnostic Ultrasound Systems
Transducer: D7L40L, Linear Array

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	P	P	P		P	P	P	P	4,5
	Small Organ[1](Specify)	P	P	P		P	P	P	P	4.5
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	P	4,5
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	N	4.5
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P	P	5

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

Note : 1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD,B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy (Super needle)

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____

System: Q6/Q8/Q9/Q10, i7/i8/i9 Diagnostic Ultrasound Systems
Transducer: D7L40L-C, Linear Array

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	N	N	N		N	N	N	N	4,5
	Small Organ[1] (Specify)	N	N	N		N	N	N	N	4,5
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	N	4,5
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	N	4.5
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	N	5

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

Note :1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD,B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy (Super needle)

Predicate transducer (K number): K101236, K120801

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____

System: Q6/Q8/Q9/Q10, i7/i8/i9 Diagnostic Ultrasound Systems
Transducer: D7L60L, Linear Array

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	P	P	P		P	P	P	P	4,5
	Small Organ[1] (Specify)	P	P	P		P	P	P	P	4,5
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	P	4.5
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	N	4.5
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P	P	5

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

Note :1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD,B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy (Super needle)

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____

System: Q6/Q8/Q9/Q10, i7/i8/i9 Diagnostic Ultrasound Systems
Transducer: D12L40L, Linear Array

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	N	N	N		N	N	N	N	4,5
	Small Organ[2] (Specify)	N	N	N		N	N	N	N	4,5
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	N	4,5
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	N	4,5
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	N	5

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

Note :1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD,B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy (Super needle)

Predicate transducer (K number): K101236

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____

System: Q6/Q8/Q9/Q10, i7/i8/i9 Diagnostic Ultrasound Systems
Transducer: D7L30L, Linear Array

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)	N	N	N		N	N	N	N	4,5
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	P	4,5
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	P	4.5
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	N	5

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

Note :1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD,B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy (Super needle)

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____

System: Q6/Q8/Q9/Q10, i7/i8/i9 Diagnostic Ultrasound Systems
Transducer: D6C12L, Micro Convex Array

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal	P	P	P		P	P	P	P	4,5
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)	P	P	P		P	P	P	P	4,5
	Other (Ob/GYN)	P	P	P		P	P	P	P	5
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel									

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

Note :1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD,B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____

System: Q6/Q8/Q9/Q10, i7/i8/i9 Diagnostic Ultrasound Systems
Transducer: D7C10L, Micro Convex Array

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal	P	P	P		P	P	P	P	4,5
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)	P	P	P		P	P	P	P	4,5
	Other (Ob/GYN)	P	P	P		P	P	P	P	5
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel									

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

Note :1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD,B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____

System: Q6/Q8/Q9/Q10, i7/i8/i9 Diagnostic Ultrasound Systems
Transducer: D7C10L-C, Micro Convex Array

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal	N	N	N		N	N	N	N	4,5
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)	N	N	N		N	N	N	N	4,5
	Other (Ob/GYN)	N	N	N		N	N	N	N	5
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel									

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

Note :1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD,B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy

Predicate transducer (K number): K101236, K120801

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____

System: Q6/Q8/Q9/Q10, i7/i8/i9 Diagnostic Ultrasound Systems
Transducer: V6C10L, Volume Probe

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal	N	N	N		N	N	N	N	3.4.5
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)	N	N	N		N	N	N	N	5
	Other (Ob/GYN)	N	N	N		N	N	N	N	5
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel									

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

Note :1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD,B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy

Predicate transducer (K number): K101236

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____

System: Q6/Q8/Q9/Q10, i7/i8/i9 Diagnostic Ultrasound Systems
Transducer: D5C20L, Micro Convex Array

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal	P	P	P		P	P	P	P	4,5
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	P	P	P		P	P	P	P	4,5
	Small Organ[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult									
	Cardiac Pediatric	P	P	P		P	P	P	P	5
Peripheral Vessel	Peripheral vessel									

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

Note : 1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD.B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____

System: Q6/Q8/Q9/Q10, i7/i8/i9 Diagnostic Ultrasound Systems
Transducer: D5C20L-A, Micro Convex Array

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal	N	N	N		N	N	N	N	4,5
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	N	N	N		N	N	N	N	4,5
	Small Organ[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult									
	Cardiac Pediatric	N	N	N		N	N	N	N	5
Peripheral Vessel	Peripheral vessel									

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

Note :1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD,B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy

Predicate transducer (K number): K101236, K120801

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____

System: Q6/Q8/Q9/Q10, i7/i8/i9 Diagnostic Ultrasound Systems
Transducer: D3C20L, Micro Convex Array

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal	N	N	N		N	N	N	N	4,5
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[II] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)	N	N	N		N	N	N	N	5
	Other (Ob/GYN)									
Cardiac	Cardiac Adult	N	N	N		N	N	N	N	5
	Cardiac Pediatric	N	N	N		N	N	N	N	5
Peripheral Vessel	Peripheral vessel									

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

Note : 1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD,B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy

Predicate transducer (K number): K101236

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____

System: Q6/Q8/Q9/Q10, i7/i8/i9 Diagnostic Ultrasound Systems
Transducer: D6C15L, Micro Convex Array

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal	P	P	P		P	P	P	P	4,5
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	N	N	N		N	N	N	N	5
	Small Organ[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel									

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

Note :1. Combined modes are B/M, B+PWD, B/Color M. B/PWD or CWD. B/Color/PWD or CWD.B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____

System: Q6/Q8/Q9/Q10, i7/i8/i9 Diagnostic Ultrasound Systems
Transducer: D6C15L-A, Micro Convex Array

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal	N	N	N		N	N	N	N	4,5
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	N	N	N		N	N	N	N	5
	Small Organ[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel									

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

Note :1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD,B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy

Predicate transducer (K number): K101236, K120801

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____

System: Q6/Q8/Q9/Q10, i7/i8/i9 Diagnostic Ultrasound Systems
Transducer: D3P64L, Phased Array

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[2] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult	P	P	P	P	P	P	P	P	5
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel									

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

Note : 1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD.B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____

System: Q6/Q8/Q9/Q10, i7/i8/i9 Diagnostic Ultrasound Systems
Transducer: D6P64L, Phased Array

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult									
	Cardiac Pediatric	P	P	P	P	P	P	P	P	5
Peripheral Vessel	Peripheral vessel									

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

Note :1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD,B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____

System: Q6/Q8/Q9/Q10, i7/i8/i9 Diagnostic Ultrasound Systems
Transducer: D2D16L, Pencil Array

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1](Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)									
	Other (Ob/GYN)									
Cardiac	Cardiac Adult				N					
	Cardiac Pediatric				N					
Peripheral Vessel	Peripheral vessel									

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

Note :1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD,B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy

Predicate transducer (K number): K101236

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____

System: Q6/Q8/Q9/Q10,i7/i8/i9 Diagnostic Ultrasound Systems
Transducer: V4C40L, Volume probe

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	P	3.
	Abdominal	P	P	P		P	P	P	P	3,4
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)	P	P	P		P	P	P	P	
	Other (Ob/GYN)	P	P	P		P	P	P	P	
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel									

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

Note :1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD,B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____

System: Q6/Q8/Q9/Q10, i7/i8/i9 Diagnostic Ultrasound Systems
Transducer: V4C40L-C, Volume Probe

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

Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Other
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	N	3.
	Abdominal	N	N	N		N	N	N	N	3.4
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ[1][1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Other (Urology)	N	N	N		N	N	N	N	
	Other (Ob/GYN)	N	N	N		N	N	N	N	
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
Peripheral Vessel	Peripheral vessel									

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

Note :1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD.B/Power/PWD
2.Small Organ: Breast, testes, thyroid
3.3D/4D Imaging Mode
4.Elastography imaging
5. Includes imaging of guidance of biopsy

Predicate transducer (K number): K101236, K120801

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____