



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

CHISON Medical Imaging Co., Ltd.  
% Mr. Bob Leiker  
Regulatory Consultant  
Leiker Regulatory & Quality Consulting  
4157 North Del Rey Avenue  
CLOVIS CA 93619

July 28, 2015

Re: K150861  
Trade/Device Name: QBit Series 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: June 11, 2015  
Received: June 30, 2015

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.

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” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

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

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a large, semi-transparent watermark of the FDA logo.

For

Robert Ochs, Ph.D.  
Acting Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

**K150861**

Device Name

QBit Series Diagnostic Ultrasound System

Indications for Use (Describe)

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

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## Diagnostic Ultrasound Indications For Use

System: QBit Series Diagnostic Ultrasound System

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	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	3,5,6
	Abdominal	N	N	N		N	N	N	3,4,5,6
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	4,5,6
	Small Organ <sup>[1]</sup> (Specify)	N	N	N		N	N	N	4,5,6
	Neonatal Cephalic	N	N	N	N	N	N	N	6,7
	Adult Cephalic	N	N	N	N	N	N	N	6,7
	Trans-rectal	N	N	N		N	N	N	4,5,6
	Trans-vaginal	N	N	N		N	N	N	3,4,5,6
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	4,5,6
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	4,5,6
Other (Urology)	N	N	N		N	N	N	5,6	
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	5,6,7
	Cardiac Pediatric	N	N	N	N	N	N	N	5,6,7
	Transesophageal	N	N	N	N	N	N	N	6,7
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	5,6

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: thyroid, testes, breast

3.3D/4D

4.Elastography

5. Includes guidance of biopsy(2D)

6.Fusion Harmonic Imaging

7.TDI

Prescription Use  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 In Vitro Diagnostics and Radiological Health (OIR)

\_\_\_\_\_  
(Division Sign Off)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: D3C60L

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	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	5,6
	Abdominal	N	N	N		N	N	N	4,5,6
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ <sup>[1]</sup> (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	5,6
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
 6.Fusion Harmonic Imaging  
 7.TDI

Prescription Use      ×      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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: D5C40L

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	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	5,6
	Abdominal	N	N	N		N	N	N	4,5,6
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ <sup>[1]</sup> (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	5,6
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
 6.Fusion Harmonic Imaging  
 7.TDI

Prescription Use      ×      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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: D3C50L

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	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	5,6
	Abdominal	N	N	N		N	N	N	4,5,6
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ <sup>[1]</sup> (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	5,6
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
 6.Fusion Harmonic Imaging  
 7.TDI

Prescription Use  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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: M3C60L

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	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	5,6
	Abdominal	N	N	N		N	N	N	4,5,6
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ <sup>[1]</sup> (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	5,6
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
 6.Fusion Harmonic Imaging  
 7.TDI

Prescription Use  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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: D7L40L

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	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	4,5,6
	Small Organ <sup>[1]</sup> (Specify)	N	N	N		N	N	N	4,5,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal	(Conventional)	N	N	N		N	N	N
(Superficial)		N	N	N		N	N	N	4,5,6
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	5,6

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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
 6.Fusion Harmonic Imaging  
 7.TDI

Prescription Use      ×      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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: M7L40L

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	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	4,5,6
	Small Organ <sup>[1]</sup> (Specify)	N	N	N		N	N	N	4,5,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	4,5,6
Musculo-skeletal (Superficial)	N	N	N		N	N	N	4,5,6	
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	5,6

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 Note : 1. Combined modes are B/M, B+PWD, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD  
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Prescription Use      ×      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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: M10L60L

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	Other	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	N	N	N		N	N	N	4,5,6	
	Small Organ <sup>[1]</sup> (Specify)	N	N	N		N	N	N	4,5,6	
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal	(Conventional)	N	N	N		N	N	N	4,5,6
(Superficial)		N	N	N		N	N	N	4,5,6	
Other (Urology)										
Cardiac		Cardiac Adult								
		Cardiac Pediatric								
	Transesophageal									
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	5,6	

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 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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
 6.Fusion Harmonic Imaging  
 7.TDI

Prescription Use  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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: D7L60L

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	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	4,5,6
	Small Organ <sup>[1]</sup> (Specify)	N	N	N		N	N	N	4,5,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	4,5,6
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	4,5,6
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	5,6

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Prescription Use  AND/OR Over-The-Counter Use   
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: D12L40L

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	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	4,5,6
	Small Organ <sup>[1]</sup> (Specify)	N	N	N		N	N	N	4,5,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	4,5,6
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	4,5,6
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	5,6

N = new indication; P = previously cleared by FDA; E = added under this appendix  
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Prescription Use  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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: D7L30L

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	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ <sup>[1]</sup> (Specify)	N	N	N		N	N	N	4,5,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal	(Conventional)	N	N	N		N	N	N
(Superficial)		N	N	N		N	N	N	4,5,6
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	5,6

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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
 6.Fusion Harmonic Imaging  
 7.TDI

Prescription Use  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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: D7L40L-REC

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	Other	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ <sup>[1]</sup> (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal		N	N	N		N	N	N	4,5,6
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Other (Urology)		N	N	N		N	N	N	5,6	
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Transesophageal									
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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
 6.Fusion Harmonic Imaging  
 7.TDI

Prescription Use      ×      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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: D6C12L

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	Other	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ <sup>[1]</sup> (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal		N	N	N		N	N	N	4,5,6
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Other (Urology)		N	N	N		N	N	N	5,6	
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Transesophageal									
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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
 6.Fusion Harmonic Imaging  
 7.TDI

Prescription Use      ×      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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: D7C10L

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	Other	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ <sup>[1]</sup> (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal		N	N	N		N	N	N	4,5,6
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Other (Urology)		N	N	N		N	N	N	5,6	
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Transesophageal									
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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
 6.Fusion Harmonic Imaging  
 7.TDI

Prescription Use      ×      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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: D7C10W

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	Other	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ <sup>[1]</sup> (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal		N	N	N		N	N	N	4,5,6
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
Musculo-skeletal (Superficial)										
Other (Urology)		N	N	N		N	N	N	5,6	
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Transesophageal									
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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
 6.Fusion Harmonic Imaging  
 7.TDI

Prescription Use      ×      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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: M7C10L

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	Other	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ <sup>[1]</sup> (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal		N	N	N		N	N	N	4,5,6
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Other (Urology)		N	N	N		N	N	N	5,6	
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Transesophageal									
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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
 6.Fusion Harmonic Imaging  
 7.TDI

Prescription Use      ×      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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: D7BC8

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	Other	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ <sup>[1]</sup> (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal		N	N	N		N	N	N	4,5,6
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Other (Urology)		N	N	N		N	N	N	5,6	
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Transesophageal									
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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
 6.Fusion Harmonic Imaging  
 7.TDI

Prescription Use      ×      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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: V6C10L

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	Other	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ <sup>[1]</sup> (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal		N	N	N		N	N	N	3,4,5,6
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
Musculo-skeletal (Superficial)										
Other (Urology)		N	N	N		N	N	N	5,6	
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Transesophageal									
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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
 6.Fusion Harmonic Imaging  
 7.TDI

Prescription Use  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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: D5C20L

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	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	N	4,5,6
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	4,5,6
	Small Organ <sup>[1]</sup> (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Other (Urology)									
Cardiac	Cardiac Adult	N	N	N		N	N	N	5,6
	Cardiac Pediatric	N	N	N		N	N	N	5,6
	Transesophageal								
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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
 6.Fusion Harmonic Imaging  
 7.TDI

Prescription Use  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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: D3C20L

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	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	N	4,5,6
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ <sup>[1]</sup> (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	5,6
Cardiac	Cardiac Adult	N	N	N		N	N	N	5,6
	Cardiac Pediatric	N	N	N		N	N	N	5,6
	Transesophageal								
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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
 6.Fusion Harmonic Imaging  
 7.TDI

Prescription Use  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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: D6C15L

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	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	5,6
	Abdominal	N	N	N		N	N	N	4,5,6
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ <sup>[1]</sup> (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	5,6
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
 6.Fusion Harmonic Imaging  
 7.TDI

Prescription Use      ×      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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: D3P64L

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	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ <sup>[1]</sup> (Specify)								
	Neonatal Cephalic								
	Adult Cephalic	N	N	N	N	N	N	N	6,7
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Other (Urology)									
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	5,6,7
	Cardiac Pediatric								
	Transesophageal								
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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
 6.Fusion Harmonic Imaging  
 7.TDI

Prescription Use      ×      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 In Vitro Diagnostics and Radiological Health (OIR)

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



System: QBit Series Diagnostic Ultrasound System

Transducer: D6P64L

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	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ <sup>[1]</sup> (Specify)								
	Neonatal Cephalic	N	N	N	N	N	N	N	6,7
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N	N	N	N	N	5,6,7
	Transesophageal								
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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
 6.Fusion Harmonic Imaging  
 7.TDI

Prescription Use  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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: D2D16L

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	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ <sup>[1]</sup> (Specify)								
	Neonatal Cephalic								
	Adult Cephalic					N			
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Other (Urology)									
Cardiac	Cardiac Adult					N			
	Cardiac Pediatric					N			
	Transesophageal								
Peripheral Vessel	Peripheral vessel					N			

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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
 6.Fusion Harmonic Imaging  
 7.TDI

Prescription Use  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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: V4C40L

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	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	3,6
	Abdominal	N	N	N		N	N	N	3,4,6
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ <sup>[1]</sup> (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	6
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
 6.Fusion Harmonic Imaging  
 7.TDI

Prescription Use      ×      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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: T5P64L

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	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ <sup>[1]</sup> (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal	N	N	N	N	N	N	N	6,7
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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
 6.Fusion Harmonic Imaging  
 7.TDI

Prescription Use      ×      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 In Vitro Diagnostics and Radiological Health (OIR)

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

System: QBit Series Diagnostic Ultrasound System

Transducer: MT5P48L

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	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ <sup>[1]</sup> (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal	N	N	N	N	N	N	N	6,7
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: thyroid, testes, breast  
 3.3D/4D  
 4.Elastography  
 5. Includes guidance of biopsy(2D)  
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Prescription Use      ×      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 In Vitro Diagnostics and Radiological Health (OIR)

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

## 510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

### 1. Submitter:

Submitter: Chison Medical Imaging Co., Ltd.  
 Address: No.228, ChangJiang East Road,Block 51 and 53,  
 Phase 5 Industrial Park, ShuoFang, New District,  
 Wuxi 214142, China  
 No.9 Xin Hui Huan Road, New District ,WuXi P.R.China  
 Contact: Ms. Ruoli Mo  
 Tel: +86-510-85311707, 85310593  
 Fax: +86-510-85310726  
 Date Prepared:February 16, 2015

### 2. Device :

**Trade Name:** QBit Series Diagnostic Ultrasound System

**Common Name:** Diagnostic Ultrasound System with Accessories

**Classification:** Regulatory Class: II  
 Review Category: Tier II

Classification 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

### 3. Predicate Device(s):

DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

510(k) Number: K132341

### 4. Device Description:

The QBit Series Diagnostic Ultrasound System is an integrated preprogrammed color doppler ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

This system is a Track 3 device that employs a wide array of probes that include linear array, convex array and phased array . This system consists of a mobile console with keyboard control panel, power supply module, color LCD monitor and optional probes.

This system is a mobile, general purpose, software controlled, color diagnostic ultrasound system. Its basic function is to acquire ultrasound echo data and to display the image B-Mode (including Fusion 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, Elastography, 3D/4D.

#### 5. Indications for Use:

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

#### 6. Summary of Non-Clinical Tests:

The QBit Series Diagnostic Ultrasound System has been evaluated for electrical, mechanical, thermal and electromagnetic compatibility safety, biocompatibility and acoustic output.

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 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

#### 7. Clinical Test:

No clinical testing was required.

#### 8. Comparison to Predicate Device:

**Table 1 Substantial Equivalence Comparison**

	<b>Predicate Device</b>	<b>Submission Device</b>	
<b>Product Name (K number)</b>	<b>DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S K132341</b>	<b>QBit Series TBD</b>	<b>Remark</b>
<b>Indications for Use</b>	Fetal Abdominal Pediatric Small Organ (breast, thyroid ,testes) Neonatal Cephalic	Fetal Abdominal Pediatric Small Organ (breast, thyroid ,testes)	Same

	Predicate Device	Submission Device	
Product Name (K number)	DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S K132341	QBit Series TBD	Remark
	Adult Cephalic Trans-rectal Trans-vaginal Musculo-skeletal( Conventional, Superficial) adult Cardiac ,pediatric Cardiac) Peripheral Vascular ; Urology Transesophageal(Cardiac)	Neonatal Cephalic ,Adult Cephalic Cephalic Transrectal Transvaginal Musculo-skeletal( Conventional, Superficial) Cardiac(adult ,pediatric) Peripheral Vascular Urology Transesophageal	
Design	Autocorrelation for color processing and FFT for pulse and CW Doppler processing. Supporting Linear, Curve , Phase array and Volume probes . Cine play back capability Image file archive	Autocorrelation for color processing and FFT for pulse and CW Doppler processing. Supporting Linear, Curve , Phase array and Volume probes . Cine play back capability Image file archive	Same
Operating Controls	TGC 8 slider	TGC 8 slider	Same
	Depth Range: 1.5 to 40 cm	Depth Range: 0 to 30 cm	SE Analysis 1
	256 shades of gray	256 shades of gray	Same
	B Dynamic range control: 30-180 dB, 5/step	B Dynamic range control: 30-180 dB, 5/step	Same
	Gain:0-100,1/step	Gain:0-255,1/step	SE Analysis 1
	Focal Number:1-4	Focal Number:1-4	Same
	Focus position: adjustable	Focus position: adjustable	Same
	B steer: available on linear transducers	B steer: available on linear transducers	Same
	B Persistence: 7 steps	B Persistence: 7 steps	Same
	ROI size/position: adjustable	ROI size/position: adjustable	Same
	Color Wall Filter settings:8 steps	Color Wall Filter settings:8 steps	Same
	Color Baseline: 16 steps	Color Baseline: 16 steps	Same
	Color Maps: 21 maps	Color Maps: 21 maps	Same
	Color Invert: on/off	Color Invert: on/off	Same
	PW sweeping speed: 6 steps	PW sweeping speed: 6 steps	Same
	PW Wall Filter: 7 steps	PW Wall Filter: 7 steps	Same
	PW sample volume: 0.5-30mm (PW only), 13 steps	PW sample volume: 0.5-30mm (PW only), 13 steps	Same
	PW angle correction: 89~89degrees, 1/step	PW angle correction: 89~89degrees, 1/step	Same
	Baseline: 8steps	Baseline: 8steps	Same

	Predicate Device	Submission Device	
<b>Product Name (K number)</b>	<b>DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S K132341</b>	<b>QBit Series TBD</b>	
	Cine control: step, play backward, play continuously	Cine control: step, play backward, play continuously	<b>Remark</b>
	Doppler Auto Trace	Doppler Auto Trace	Same
	Freeze control:Toggling freeze key	Freeze control:Toggling freeze key	Same
<b>Safety Compliance</b>	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 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	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 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	Same
<b>Patient Contact Materials</b>	Bio-compatible	Bio-compatible	Same
<b>Operation Mode</b>	B, THI,PSH (Phase Shift Harmonic Imaging) , M,Color M, Free Xros MTM (Anatomical M-mode), Free Xros CM (Curved Anatomical M-mode), Color Doppler Imaging,Power Doppler Imaging/Directional PD, Pulsed Wave Doppler, Continuous Wave Doppler , TDI, UWN+(Ultra Wideband Non-linear) Contrast Imaging, 3D/ 4D ,Elastography, iScape View (Panoramic Imaging )	B, FHI, M,Color M, Free Steering M mode , Color Doppler Imaging,Power Doppler Imaging/Directional PD, Pulsed Wave Doppler, Continuous Wave Doppler , TDI, Contrast Imaging, 3D/4D ,Elastography, Curved Panoramic ,Trapezoidal image	Same
<b>Display Modes</b>	B,M,PW,CW,CFM,Power/Dirpower ,TDI,3D/4D; B+M,B+PW,B+CFM,B+PD/DPD, B+CFM+PW/CW,B+PW+PD/DPD	B,M,PW,CW,CFM,Power/Dirpower ,TDI,3D/4D; B+M,B+PW,B+CFM,B+PD/DPD, B+CFM+PW/CW,B+PW+PD/DPD	Same

	Predicate Device	Submission Device	
<b>Product Name (K number)</b>	<b>DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S K132341</b>	<b>QBit Series TBD</b>	<b>Remark</b>
<b>Display Annotations</b>	Logo; Hospital Name;Exam date;Exam time; Acoustic Power ;Mechanical index;Tissue thermal indes;ID,Last name,First Name,Middle initial,Gender,Age;Probe model;ECG ico;Operator;TGC Corve;Focus position;Thumbnail;Imaging parameters;Dynamic Trackball indices	Logo; Hospital Name;Exam date;Exam time; Acoustic Power ;Mechanical index;Tissue thermal indes;ID,Last name,First Name,Middle initial,Gender,Age;Probe model;ECG ico;Operator;TGC Corve;Focus position;Thumbnail;Imaging parameters;Dynamic Trackball indices	Same
<b>Display Monitor</b>	19" high-resolution color LCD monitor	15"/ 19" high-resolution color LCD monitor	Same
<b>Measurements</b>	<b>2D mode:</b> Depth , Distance ,Area: Ellipse, Trace, Spline, Cross,Trace Length , Double Distance , Parallel ,Volume :Distance, Ellipse, Ellipse + Distance,Length Ratio ,Area Ratio , IMT, B Histogram , B, Profile, Volume Flow, Color Velocity; <b>M mode:</b> Distance,Time, Slope, Heart Rate,Velocity; <b>Doppler mode:</b> D Velocity ,Time ,Heart Rate,Acceleration ,D Trace,PS/ED , Volume Flow;	<b>2D mode:</b> Depth , Distance ,Area: Ellipse, Trace, Spline, Trace Length , Double Distance , Parallel ,Volume :Distance, Ellipse, Ellipse + Distance, Distance Ratio ,Area Ratio , IMT, Volume Flow, Color Velocity; <b>M mode:</b> Distance,Time, Slope, Heart Rate,Velocity; <b>Doppler mode:</b> D Velocity ,Time ,Heart Rate,Acceleration ,D Trace,PS/ED , Volume Flow;	Same
<b>Transducer Types &amp; Connectors</b>	Convex Array, Phased Array, Linear Array,Volume probe 4 ports	Convex Array, Phased Array, Linear Array,Volume probe 4 ports	Same
<b>Users Sites</b>	Hospitals, clinics usage	Hospitals, clinics usage	Same
<b>Acoustic Output</b>	Track 3; MI, TIS, TIC, TIB Derated Ispta: 720mW/cm <sup>2</sup> maximum, TIS/TIB/TIC:0.1-4.0 Range, Mechanical Index: 1.94.0 Maximum, or Derated Isppa: 190 W/cm <sup>2</sup> max	Track 3; MI, TIS, TIC, TIB Derated Ispta: 720mW/cm <sup>2</sup> maximum, TIS/TIB/TIC:0.1-4.0 Range, Mechanical Index: 1.94.0 Maximum, or Derated Isppa: 190 W/cm <sup>2</sup> max	Same

	Predicate Device	Submission Device	
<b>Product Name (K number)</b>	<b>DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S K132341</b>	<b>QBit Series TBD</b>	<b>Remark</b>
<b>Power Requirements</b>	Power requirements: AC: 100-127V,or 220-240v Frequency: 50/60 Hz Operating temperature: 0-40° C; relative humidity 30-85%; Barometric pressure:700 to 1060 hPa	Power requirements: AC :100V- 240V, Frequency:50-60Hz Operating temperature: 10-40° C; relative humidity 30-75%; Barometric pressure:700 to 1060 hPa	SE Analysis 2

## Comparison Analysis

### SE Analysis 1

The Operating Controls item of proposed device and the predicate device are with different Image Depth Range and Gain , but they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

### SE Analysis 2

The Power Supply of the proposed device and the predicate device are AC :100V- 240V and 100-127V,or 220-240V , but both them comply with the requirements of IEC60601-1 and include the voltage range in the United States. Therefore they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected. Therefore, power supply can be considered Substantially Equivalent in safety and effectiveness.

### Conclusion:

In accordance with the Act. 21 CFR Part 807 and based on the information provided in this premarket notification, Chison Medical Imaging Co., Ltd. concludes that the QBit Series Diagnostic Ultrasound System is substantially equivalent to the predicate devices with regard to safety and effectiveness.

### 9. Substantially Equivalent Conclusion:

In accordance with the Act. 21 CFR Part 807 and based on the information provided in this premarket notification, Chison Medical Imaging Co., Ltd. concludes that the QBit Series Diagnostic Ultrasound System is substantially equivalent to the predicate devices with regard to safety and effectiveness.