



CHISON Medical Technologies Co., Ltd.
% Mr. Liu Qifei
Regulatory Affairs Manager
No.228, Changjiang East Road, Block 51 and 53, Phase 5,
Shuofang Industrial Park
Xinwu District, Wuxi, Jiangsu 214142
CHINA

August 17, 2018

Re: K180974

Trade/Device Name: CBit Series Digital Color Doppler Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: July 5, 2018
Received: July 9, 2018

Dear Mr. Qifei:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

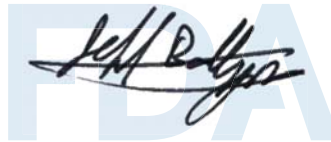
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



for
Robert Ochs, Ph.D.
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)

K180974

Device Name

CBit Series Digital Color Doppler Ultrasound System

Indications for Use (Describe)

The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified clinician for evaluation of Fetal ,Abdominal,Pediatric,Small Organ (breast, thyroid, testes), Neonatal Cephalic ,Adult Cephalic,Cardiac (adult , pediatric),Musculo-skeletal (Conventional , Superficial) ,Peripheral Vascular,Trans-esophageal,Trans-rectal, Trans-vaginal, OB/GYN and 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: CBit Series Digital Color Doppler 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	3,4,6,7
	Abdominal	N	N	N		N	N	N	3,5,6,7
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	3,5,6,7
	Small Organ ^[1] (Specify)	N	N	N		N	N	N	
	Neonatal Cephalic	N	N	N	N	N	N	N	3,6,7,8
	Adult Cephalic	N	N	N	N	N	N	N	3,6,7,8
	Trans-rectal	N	N	N		N	N	N	3,5,6,7
	Trans-vaginal	N	N	N		N	N	N	3,4,5,6,7
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	3,5,6,7
Musculo-skeletal (Superficial)	N	N	N		N	N	N	3,5,6,7	
Other (OB/GYN)	N	N	N		N	N	N	3,5,6,7	
Other (Urology)	N	N	N		N	N	N	3,5,6,7	
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	3,6,7,8
	Cardiac Pediatric	N	N	N	N	N	N	N	3,6,7,8
	Transesophageal	N	N	N	N	N	N	N	3,7,8
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	3,5,6,7

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Note : 1. Combined modes are B/M, B/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler 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	3,6,7	
	Abdominal	N	N	N		N	N	N	3,5,6,7	
	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)		N	N	N		N	N	N	3,5,6,7
	Musculo-skeletal (Superficial)									
Other (OB/GYN)		N	N	N		N	N	N	3,5,6,7	
Other (Urology)		N	N	N		N	N	N	3,5,6,7	
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Transesophageal									
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	3,5,6,7	

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Note : 1. Combined modes are B/M, B/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler 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	3,6,7	
	Abdominal	N	N	N		N	N	N	3,5,6,7	
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	N	N	N		N	N	N	3,5,6,7	
	Small Organ ^[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)		N	N	N		N	N	N	3,5,6,7
	Musculo-skeletal (Superficial)									
Other (OB/GYN)		N	N	N		N	N	N	3,5,6,7	
Other (Urology)		N	N	N		N	N	N	3,5,6,7	
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Transesophageal									
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	3,5,6,7	

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Note : 1. Combined modes are B/M, B/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler 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	3,6,7	
	Abdominal	N	N	N		N	N	N	3,5,6,7	
	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)		N	N	N		N	N	N	3,5,6,7
	Musculo-skeletal (Superficial)									
Other (OB/GYN)		N	N	N		N	N	N	3,5,6,7	
Other (Urology)		N	N	N		N	N	N	3,5,6,7	
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Transesophageal									
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	3,5,6,7	

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Note : 1. Combined modes are B/M, B/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler 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	3,6,7	
	Abdominal	N	N	N		N	N	N	3,5,6,7	
	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)		N	N	N		N	N	N	3,5,6,7
	Musculo-skeletal (Superficial)									
Other (OB/GYN)		N	N	N		N	N	N	3,5,6,7	
Other (Urology)		N	N	N		N	N	N	3,5,6,7	
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Transesophageal									
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	3,5,6,7	

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Note : 1. Combined modes are B/M, B/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler Ultrasound System
 Transducer: H3C60L

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	3,6,7	
	Abdominal	N	N	N		N	N	N	3,5,6,7	
	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)		N	N	N		N	N	N	3,5,6,7
	Musculo-skeletal (Superficial)									
Other (OB/GYN)		N	N	N		N	N	N	3,5,6,7	
Other (Urology)		N	N	N		N	N	N	3,5,6,7	
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Transesophageal									
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	3,5,6,7	

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Note : 1. Combined modes are B/M, B/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler 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	N	N	N		N	N	N	3,5,6,7
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	3,5,6,7
	Small Organ ^[1] (Specify)	N	N	N		N	N	N	3,5,6,7
	Neonatal Cephalic	N	N	N		N	N	N	3,6,7
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	3,5,6,7
Musculo-skeletal (Superficial)	N	N	N		N	N	N	3,5,6,7	
Other (OB/GYN)									
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	3,5,6,7

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Note : 1. Combined modes are B/M, B/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler 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	N	N	N		N	N	N	3,5,6,7
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	3,5,6,7
	Small Organ ⁽¹⁾ (Specify)	N	N	N		N	N	N	3,5,6,7
	Neonatal Cephalic	N	N	N		N	N	N	3,6,7
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	3,5,6,7
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	3,5,6,7
Other (OB/GYN)									
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	3,5,6,7

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Note : 1. Combined modes are B/M, B/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler Ultrasound System
Transducer: M8L40L

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

Table with columns: Clinical Application (General, Specific), Mode of Operation (B, M, PW Doppler, CW Doppler, Color Doppler, Power Doppler, Combined Modes, Other). Rows include Ophthalmic, Fetal Imaging & Other, Cardiac, and Peripheral Vessel.

N = new indication; P = previously cleared by FDA; E = added under this appendix
Note : 1. Combined modes are B/M, B/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
2. Small Organ: thyroid, testes, breast
3.3D
4.4D
5. Elastography
6. Includes guidance of biopsy (2D)
7. Fusion Harmonic Imaging
8.TDI

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 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: CBit Series Digital Color Doppler Ultrasound System
 Transducer: M8L60L

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	3,5,6,7
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	3,5,6,7
	Small Organ ^[1] (Specify)	N	N	N		N	N	N	3,5,6,7
	Neonatal Cephalic	N	N	N		N	N	N	3,6,7
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	Musculo-skeletal (Conventional)	N	N	N		N	N	N
Musculo-skeletal (Superficial)		N	N	N		N	N	N	3,5,6,7
Other (OB/GYN)									
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	3,5,6,7

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Note : 1. Combined modes are B/M, B/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler Ultrasound System
 Transducer: D10L30L

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	3,5,6,7
	Small Organ ^[1] (Specify)	N	N	N		N	N	N	3,5,6,7
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	3,5,6,7
Musculo-skeletal (Superficial)	N	N	N		N	N	N	3,5,6,7	
Other (OB/GYN)									
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	3,5,6,7

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Note : 1. Combined modes are B/M, B/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler Ultrasound System
 Transducer: D8L50L

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	3,5,6,7
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	3,5,6,7
	Small Organ ^[1] (Specify)	N	N	N		N	N	N	3,5,6,7
	Neonatal Cephalic	N	N	N		N	N	N	3,6,7
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	3,5,6,7
Musculo-skeletal (Superficial)	N	N	N		N	N	N	3,5,6,7	
Other (OB/GYN)									
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	3,5,6,7

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Note : 1. Combined modes are B/M, B/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler 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 ^[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal		N	N	N		N	N	N	3,5,6,7
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Other (OB/GYN)										
Other (Urology)		N	N	N		N	N	N	3,5,6,7	
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/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler 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 ⁽¹⁾ (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal		N	N	N		N	N	N	3,5,6,7
	Trans-vaginal		N	N	N		N	N	N	3,4,5,6,7
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Other (OB/GYN)		N	N	N		N	N	N	3,5,6,7	
Other (Urology)		N	N	N		N	N	N	3,5,6,7	
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/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler 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 ^[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal		N	N	N		N	N	N	3,5,6,7
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Other (OB/GYN)		N	N	N		N	N	N	3,5,6,7	
Other (Urology)		N	N	N		N	N	N	3,5,6,7	
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/CFM, B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler Ultrasound System
 Transducer: D6C10L

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 ^[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal		N	N	N		N	N	N	3,5,6,7
	Trans-vaginal		N	N	N		N	N	N	3,5,6,7
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Other (OB/GYN)		N	N	N		N	N	N	3,5,6,7	
Other (Urology)		N	N	N		N	N	N	3,5,6,7	
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/CFM, B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler 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 ^[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal		N	N	N		N	N	N	3,5,6,7
	Trans-vaginal		N	N	N		N	N	N	3,5,6,7
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Other (OB/GYN)		N	N	N		N	N	N	3,5,6,7	
Other (Urology)		N	N	N		N	N	N	3,5,6,7	
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/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler 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 ^[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal		N	N	N		N	N	N	3,5,6,7
	Trans-vaginal		N	N	N		N	N	N	3,5,6,7
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Other (OB/GYN)		N	N	N		N	N	N	3,5,6,7	
Other (Urology)		N	N	N		N	N	N	3,5,6,7	
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/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler 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 ^[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal		N	N	N		N	N	N	3,5,6,7
	Trans-vaginal		N	N	N		N	N	N	3,5,6,7
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
Musculo-skeletal (Superficial)										
Other (OB/GYN)		N	N	N		N	N	N	3,5,6,7	
Other (Urology)		N	N	N		N	N	N	3,5,6,7	
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/CFM, B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler 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 ⁽¹⁾ (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal		N	N	N		N	N	N	3,5,6,7
	Trans-vaginal		N	N	N		N	N	N	3,5,6,7
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Other (OB/GYN)		N	N	N		N	N	N	3,5,6,7	
Other (Urology)		N	N	N		N	N	N	3,5,6,7	
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/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler 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	N	N	N		N	N	N	3,6,7
	Abdominal	N	N	N		N	N	N	3,5,6,7
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	3,5,6,7,8
	Small Organ ⁽¹⁾ (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	Musculo-skeletal (Conventional)	N	N	N		N	N	N
Musculo-skeletal (Superficial)									
Other (OB/GYN)		N	N	N		N	N	N	3,5,6,7
Other (Urology)		N	N	N		N	N	N	3,5,6,7
Cardiac	Cardiac Adult	N	N	N		N	N	N	3,6,7,8
	Cardiac Pediatric	N	N	N		N	N	N	3,6,7,8
	Transesophageal								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	3,5,6,7

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Note : 1. Combined modes are B/M, B/CFM, B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler 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	3,5,6,7
	Abdominal	N	N	N		N	N	N	3,5,6,7
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	3,5,6,7,8
	Small Organ ^[1] (Specify)								
	Neonatal Cephalic	N	N	N		N	N	N	3,6,7
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Other (OB/GYN)									
Other (Urology)		N	N	N		N	N	N	3,5,6,7
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N		N	N	N	3,6,7,8
	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/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler 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	N	N	N		N	N	N	3,5,6,7
	Abdominal	N	N	N		N	N	N	3,5,6,7
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	3,5,6,7,8
	Small Organ ⁽¹⁾ (Specify)								
	Neonatal Cephalic	N	N	N		N	N	N	3,6,7
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Other (OB/GYN)									
Other (Urology)		N	N	N		N	N	N	3,5,6,7
Cardiac	Cardiac Adult	N	N	N		N	N	N	3,6,7,8
	Cardiac Pediatric	N	N	N		N	N	N	3,6,7,8
	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/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler 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	N	N	N		N	N	N	3,6,7
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ ^[1] (Specify)								
	Neonatal Cephalic	N	N	N	N	N	N	N	3,6,7,8
	Adult Cephalic	N	N	N	N	N	N	N	3,6,7,8
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
Musculo-skeletal (Superficial)									
Other (OB/GYN)									
Other (Urology)									
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	3,6,7,8
	Cardiac Pediatric	N	N	N	N	N	N	N	3,6,7,8
	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/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler Ultrasound System
 Transducer: D3P64LS

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	3,6,7
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ ⁽¹⁾ (Specify)								
	Neonatal Cephalic	N	N	N	N	N	N	N	3,6,7,8
	Adult Cephalic	N	N	N	N	N	N	N	3,6,7,8
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
Musculo-skeletal (Superficial)									
Other (OB/GYN)									
Other (Urology)									
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	3,6,7,8
	Cardiac Pediatric	N	N	N	N	N	N	N	3,6,7,8
	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/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler Ultrasound System
 Transducer: D2P64L

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	3,6,7
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ ^[1] (Specify)								
	Neonatal Cephalic	N	N	N	N	N	N	N	3,6,7,8
	Adult Cephalic	N	N	N	N	N	N	N	3,6,7,8
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
Musculo-skeletal (Superficial)									
Other (OB/GYN)									
Other (Urology)									
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	3,6,7,8
	Cardiac Pediatric	N	N	N	N	N	N	N	3,6,7,8
	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/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler Ultrasound System
 Transducer: D5P64L

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	3,6,7
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	3,6,7,8
	Small Organ ^[1] (Specify)								
	Neonatal Cephalic	N	N	N	N	N	N	N	3,6,7,8
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
Musculo-skeletal (Superficial)									
Other (OB/GYN)									
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N	N	N	N	N	3,6,7,8
	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/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.TDI

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: CBit Series Digital Color Doppler 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 ^[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic					N			
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Other (OB/GYN)									
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/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler 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	3,4,7
	Abdominal	N	N	N		N	N	N	3,4,7
	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 (OB/GYN)		N	N	N		N	N	N	3,4,7
Other (Urology)		N	N	N		N	N	N	3,4,7
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/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler 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 ⁽¹⁾ (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Other (OB/GYN)									
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal	N	N	N	N	N	N	N	3,7,8
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/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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: CBit Series Digital Color Doppler 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 ⁽¹⁾ (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Other (OB/GYN)									
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Transesophageal	N	N	N	N	N	N	N	3,7,8
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/CFM , B/PD, B/DPD, B/PW or CW, B/Color M, B/BC,B/CFM/PW or CW,B/PD or DPD/PW or CW
 2. Small Organ: thyroid, testes, breast
 3.3D
 4.4D
 5. Elastography
 6. Includes guidance of biopsy (2D)
 7. Fusion Harmonic Imaging
 8.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)

510(k) Summary

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

1. Submitter:

Submitter: CHISON Medical Technologies Co., Ltd.
 Address: No.228, Changjiang East Road, Block 51 and 53, Phase 5, Shuofang Industrial Park, Xinwu District, Wuxi, Jiangsu, China 214142
 No.9, Xinhuihuan Road, Xinwu District, Wuxi, Jiangsu, China 214028
 Contact: Mr. Liu Qifei
 Tel: +86-510-85310019
 Fax: +86-510-85310021
 Date Prepared: March 29, 2018

2. Device :

Trade Name: CBit Series Digital Color Doppler Ultrasound System

Common Name: Diagnostic Ultrasound System with Transducers

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):

Device	Manufacturer	Model	510(k)Number
1.Main predicate device	CHISON	SonoBook 9	K170374
2.Reference device	CHISON	QBit 9	K150861

4. Device Description:

The CBit Series Digital Color Doppler 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 clinician for evaluation of Fetal , Abdominal, Pediatric, Small Organ (breast, thyroid, testes), Neonatal Cephalic ,Adult Cephalic, Cardiac (adult , pediatric), Musculo-skeletal (Conventional, Superficial),Peripheral Vascular, Trans-esophageal, Trans-rectal,Trans-vaginal, OB/GYN and Urology.

6. Summary of Non-Clinical Tests:

The CBit Series Digital Color Doppler 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: 2014 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.

Software Documentation for a Moderate Level of Concern, per the FDA guidance document,"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document issued on May 11, 2005", is also included as part of this submission.

8. Comparison to Predicate Device:

Table 1 Substantial Equivalence Comparison

Items	Main predicate device	Reference device	Submission Device	Remark
		SonoBook 9 Diagnostic Ultrasound System K170374.	QBit 9 Diagnostic Ultrasound System K150861	
Indications for Use	Fetal Abdominal	Fetal Abdominal	Fetal Abdominal	SE Analysis 1

Items	Main predicate device	Reference device	Submission Device	Remark
	SonoBook 9 Diagnostic Ultrasound System K170374.	QBit 9 Diagnostic Ultrasound System K150861	CBIT Series Digital Color Doppler Ultrasound System	
	Pediatric Small Organ (breast, thyroid ,testes) Neonatal Cephalic ,Adult Cephalic Trans-rectal Trans-vaginal Musculo-skeletal(Conventional, Superficial) Cardiac(adult ,pediatric) Peripheral Vascular Urology Trans-esophageal	Pediatric Small Organ (breast, thyroid ,testes) Neonatal Cephalic ,Adult Cephalic Trans-rectal Trans-vaginal Musculo-skeletal(Conventional, Superficial) Cardiac(adult ,pediatric) Peripheral Vascular Urology Trans-esophageal	Pediatric Small Organ (breast, thyroid ,testes) Neonatal Cephalic ,Adult Cephalic Trans-rectal Trans-vaginal Musculo-skeletal(Conventional, Superficial) Cardiac(adult ,pediatric) Peripheral Vascular OB/GYN,Urology Trans-esophageal	
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	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	TGC 8 slider	Same
	Depth Range: 0 to 30 cm	Depth Range: 0 to 30 cm	Depth Range: 0 to 45 cm	SE Analysis 2
	256 shades of gray	256 shades of gray	256 shades of gray	Same
	B Dynamic range control: 60-165 dB, 7/step	B Dynamic range control: 30-180 dB, 5/step	B Dynamic range control: 20-280dB	SE Analysis 2
	Gain:0-255,1/step	Gain:0-255,1/step	Gain:0-255,1/step	Same
	Focal Number: adjustable	Focal Number: adjustable	Focal Number: adjustable	Same
	Focus position: adjustable	Focus position: adjustable	Focus position: adjustable	Same
	B steer: available on linear transducers	B steer: available on linear transducers	B steer: available on linear transducers	Same
	B Persistence: 7 steps	B Persistence: 7 steps	B Persistence: 7 steps	Same
	ROI size/position: adjustable	ROI size/position: adjustable	ROI size/position: adjustable	Same
	Color Wall Filter settings:4 steps	Color Wall Filter settings:8 steps	Color Wall Filter settings:8 steps	Same
	Color Baseline: 7 steps	Color Baseline: 16 steps	Color Baseline: 16 steps	Same
Color Maps: 11 maps	Color Maps: 21 maps	Color Maps: 21 maps	Same	

Items	Main predicate device	Reference device	Submission Device	Remark
	SonoBook 9 Diagnostic Ultrasound System K170374.	QBit 9 Diagnostic Ultrasound System K150861	CBit Series Digital Color Doppler Ultrasound System	
	Color Invert: on/off	Color Invert: on/off	Color Invert: on/off	Same
	PW sweeping speed: 3steps	PW sweeping speed: 6 steps	PW sweeping speed: 6 steps	Same
	PW Wall Filter: 4 steps	PW Wall Filter: 7 steps	PW Wall Filter: 7 steps	Same
	PW sample volume: 1-8mm (PW only), 8 steps	PW sample volume: 0.5-30mm (PW only), 13 steps	PW sample volume: 0.5-30mm (PW only)	Same
	PW angle correction:-80~80degrees, 5/step	PW angle correction:-89~89degrees, 1/step	PW angle correction:-89~89degrees, 1/step	Same
	Baseline: 7steps	Baseline: 8steps	Baseline: 8steps	Same
	Cine control: step, play backward, play continuously	Cine control: step, play backward, play continuously	Cine control: step, play backward, play continuously	Same
	Doppler Auto Trace	Doppler Auto Trace	Doppler Auto Trace	Same
	Freeze control:Toggling freeze key	Freeze control:Toggling freeze key	Freeze control:Toggling freeze key	Same
Safety Compliance	IEC60601-1 IEC60601-1-2 ISO 10993-1 ISO 10993-5 ISO 10993-10 AIUM/ NEMA UD2 AIUM/ NEMA UD3	IEC60601-1 IEC60601-1-2 ISO 10993-1 ISO 10993-5 ISO 10993-10 AIUM/ NEMA UD2 AIUM/ NEMA UD3	IEC60601-1 IEC60601-1-2 ISO 10993-1 ISO 10993-5 ISO 10993-10 AIUM/ NEMA UD2 AIUM/ NEMA UD3	Same
Operation Mode	B mode	B mode	B mode	Same
	B/M mode	B/M mode	B/M mode	Same
	M mode	M mode	M mode	Same
	Dual mode	Dual mode	Dual mode	Same
	Quad mode	Quad mode	Quad mode	Same
	CFM mode	CFM mode	CFM mode	Same
	CPA mode	PD mode	CPA mode	Same
	DPD mode	DPD mode	DPD mode	Same
	PW mode	PW mode	PW mode	Same
	B/BC mode	B/BC mode	B/BC mode	Same
	2D Steer	2D Steer	2D Steer	Same
	Triplex mode	Triplex	Triplex mode	Same
	Quadplex	Quadplex	Quadplex	Same
	Free Hand 3D	--	HD 3D	Same
	CW mode	CW mode	CW mode	Same
	Free Steering M mode	Free Steering M mode	Free Steering M mode	Same
	HPRF	HPRF	HPRF	Same
	B-Flow	--	S-flow	Same
	AutoTGC	--	Auto TGC	Same
	Stress Echo	--	Stress echo	Same
	Strain	--	Strain	Same

Items	Main predicate device	Reference device	Submission Device	Remark
	SonoBook 9 Diagnostic Ultrasound System K170374.	QBit 9 Diagnostic Ultrasound System K150861	CBit Series Digital Color Doppler Ultrasound System	
	TDI	TDI	TDI	Same
	Color M mode	Color M mode	Color M mode	Same
	Curved Panoramic	Curved Panoramic	Curved Panoramic	Same
	Trapezoidal mode	Trapezoidal image	Trapezoidal image	Same
	Compound	compound	compound	Same
	SRA	SRA	SRA	Same
	Chroma		Chroma	Same
	Elastography	Elastography	Elastography	Same
	ECG	ECG	ECG	Same
	--	--	LV tracking	SE Analysis 3
	--	--	LGC	SE Analysis 4
	Auto IMT	Auto IMT	Auto IMT	Same
	Auto NT	---	Free NT	Same
	Super Needle	Super Needle	Super Needle	Same
	General measurement package	general measurement package	general measurement package	Same
	OB measurement package	OB measurement package	OB measurement package	Same
	GYN measurement package	GYN measurement package	GYN measurement package	Same
	URO measurement package	URO measurement package	URO measurement package	Same
	Cardiac measurement package	cardiac measurement package	cardiac measurement package	Same
	Vascular measurement package	vascular measurement package	vascular measurement package	Same
	Small parts measurement package	small parts measurement package	small parts measurement package	Same
	Pediatric measurement package	Pediatric measurement package	Pediatric measurement package	Same
	TCD measurement package	--	TCD measurement package	Same
	4D software package	4D software package	4D software package	Same
	--	--	Breast measurement package	SE Analysis 5
	Virtual HD	Virtual HD	Virtual HD	Same
	X-Contrast	X-Contrast	X-Contrast	Same
	FHI	FHI	FHI	Same
	Q-Image	Q-image	Q-image	Same
	Q-flow	Q-flow	Q-flow	Same
	Q-beam	Q-beam	Q-beam	Same
	AIO	AIO	AIO	Same

Items	Main predicate device	Reference device	Submission Device	Remark
	SonoBook 9 Diagnostic Ultrasound System K170374.	QBit 9 Diagnostic Ultrasound System K150861	CBit Series Digital Color Doppler Ultrasound System	
Display Annotations	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;Imagin g parameters;Dynamic Trackball indices	Logo; Hospital Name;Exam date;Exam time; Acoustic Power ;Mechanical index;Thermal indes;Probe model;ECG ico;TGC Corve;Focus position;Imaging parameters;Dynamic Trackball indices; System status;Gray/Color bar	Logo; Hospital Name;Exam date;Exam time; Acoustic Power ;Mechanical index;Thermal indes;Probe model;ECG ico;TGC Corve;Focus position;Imaging parameters;Dynamic Trackball indices; System status;Gray/Color bar	Same
Measurements	2D mode: Depth , Distance ,Area: Ellipse, Trace, Spline, Trace Length , Volume :Distance, Ellipse, Ellipse + Distance, Distance Ratio ,Area Ratio , IMT, Volume Flow, M mode: Distance,Time, Heart Rate,Velocity; Doppler mode: D Velocity ,Time ,Heart Rate,Acceleration ,D Trace,PS/ED , Volume Flow;	2D mode: Depth , Distance ,Area: Ellipse, Trace, Spline, Trace Length , Double Distance , Parallel ,Volume :Distance, Ellipse, Ellipse + Distance,Length Ratio ,Area Ratio , IMT, B Histogram , B Profile, Volume Flow, Color Velocity; M mode: Distance,Time, Slope, Heart Rate,Velocity; Doppler mode: D Velocity ,Time ,Heart Rate,Acceleration ,D Trace,PS/ED , Volume Flow;	2D mode: 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; M mode: Distance,Time, Slope, Heart Rate,Velocity; Doppler mode: D Velocity ,Time ,Heart Rate,Acceleration ,D Trace,PS/ED , Volume Flow;	Same
Transducer Types & Connectors	Convex Array, Phased Array, Linear Array,Volume probe 1 ports	Convex Array, Phased Array, Linear Array,Volume probe 4ports	Convex Array, Phased Array, Linear Array,Volume probe 4ports	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, TIS/TIB/TIC:0.1-4.0 Range, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190 W/cm ² max	Track 3; MI, TIS, TIC, TIB Derated Ispta: 720mW/cm ² maximum, TIS/TIB/TIC:0.1-4.0 Range, Mechanical Index: 1.9 Maximum,	Track 3; MI, TIS, TIC, TIB Derated Ispta: 720mW/cm ² maximum, TIS/TIB/TIC:0.1-4.0 Range, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190	Same

Items	Main predicate device	Reference device	Submission Device	Remark
		SonoBook 9 Diagnostic Ultrasound System K170374.	QBit 9 Diagnostic Ultrasound System K150861	
		or Derated Isppa: 190 W/cm ² max	W/cm ² max	
Power Requirements	Power requirements: AC :100V- 240V, Frequency:50-60Hz Operating temperature:10-40 °C ; relative humidity 30-75%; 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	Power requirements: AC :100V- 240V, Frequency:50-60Hz Operating temperature:10-40 °C ; relative humidity 30-75%; Barometric pressure:700 to 1060 hPa	Same

Comparison Analysis

SE Analysis 1:

Indication for use, compared with the predicate device, the subject device has some differences in presenting OB/GYN.

OB/GYN is short for obstetrics/gynecology. Both predicate and subject device contain OB measurement package and GYN measurement package. OB/GYN application can be seen as part of Fetal, Abdominal and Trans-vaginal applications in some degree. Both of the predicate and subject device comply with the requirements of IEC60601-1 & IEC60601-2-37 and meet clinical requirements. Therefore they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

SE Analysis 2:

Operation mode, compared with the predicate device, the subject device employs the same operation controls design and has some differences in value range. But both of them comply with the requirements of IEC60601-1 & IEC60601-2-37 and meet clinical requirements. Therefore they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

SE Analysis 3:

Operation mode, compared with the predicate device, the subject device employs the same operation controls design and has some differences in presenting LV tracking.

LV tracking is a non-invasive method for the assessment of left ventricular(LV) function. The relevant measurement items are IVSd, LVIDd, LVPWd, IVSs, LVIDs, LVPWs, LVLd, LVLs, LVAMd, LVAMs, LVAPd, LVAPs, EDV and ESV, of which are all under cardiac measurement

package. Both predicate and submission device contain cardiac measurement package. Both of the predicate and subject device comply with the requirements of IEC60601-1 & IEC60601-2-37 and meet clinical requirements. Therefore they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

SE Analysis 4:

Operation mode, compared with the predicate device, the subject device employs the same operation controls design and has some differences in presenting LGC. LGC (Lateral Gain Compensation) consists of the same tabular array as TGC, which is contained in predicate and submission device. The only difference is that the array is arranged horizontally by LGC while vertically by TGC. The goal of LGC is to have control over the image brightness from side to side.

Both of the predicate and subject device comply with the requirements of IEC60601-1 & IEC60601-2-37 and meet clinical requirements. Therefore they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

SE Analysis 5:

Operation Controls, compared with the predicate device, the subject device employs the same operation controls design and has some differences in presenting Breast measurement package. Breast measurement is under the small parts measurement package in B mode, including length, height, width and volume measurement items. Both predicate and submission device contain small parts (breast, thyroid, testes) measurement package.

Both of the predicate and subject device comply with the requirements of IEC60601-1 & IEC60601-2-37 and meet clinical requirements. Therefore they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

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 Technologies Co., Ltd. concludes that the CBit Series Digital Color Doppler Ultrasound System is substantially equivalent to the predicate devices with regard to safety and effectiveness.