



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

Chison Medical Imaging Co., Ltd.
% Bob Leiker
Leiker Regulatory & Quality
4157 North Del Rey Ave
CLOVIS, CA 93619

June 6, 2017

Re: K170374
Trade/Device Name: SonoBook 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: April 27, 2017
Received: May 3, 2017

Dear Mr. Bob 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 "Robert Ochs, Ph.D.". The signature is written in a cursive style. In the background, there is a large, faint, light blue watermark of the letters "FDA".

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)

K170374

Device Name

SonoBook 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Diagnostic Ultrasound Indications For Use

System: SonoBook 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 ^[1] (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	4,5,6
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/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/4D
4. Elastography
5. Includes guidance of biopsy (2D)
6. Fusion Harmonic Imaging
7. 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: SonoBook Series Diagnostic Ultrasound System

Transducer: C3-V

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 ^[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Other (Urology)	N	N	N		N	N	N	4,5,6
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/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/4D

4. Elastography

5. Includes guidance of biopsy (2D)

6. Fusion Harmonic Imaging

7. 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: SonoBook Series Diagnostic Ultrasound System
 Transducer: C3M-V

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 ^[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Other (Urology)	N	N	N		N	N	N	4,5,6
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/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/4D

4. Elastography

5. Includes guidance of biopsy (2D)

6. Fusion Harmonic Imaging

7. TDI

Prescription Use X
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
 (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: SonoBook Series Diagnostic Ultrasound System

Transducer: C3T-V

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 ^[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Other (Urology)	N	N	N		N	N	N	4,5,6	
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/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/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: SonoBook Series Diagnostic Ultrasound System

Transducer: L7-V

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 ^[1] (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

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/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: SonoBook Series Diagnostic Ultrasound System

Transducer: L7SVA-V

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 ^[1] (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

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/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: SonoBook Series Diagnostic Ultrasound System

Transducer: L8Mb-V

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 ^[1] (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

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/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: SonoBook Series Diagnostic Ultrasound System

Transducer: L8M-V

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 ^[1] (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

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/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: SonoBook Series Diagnostic Ultrasound System

Transducer: L12-V

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 ^[1] (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

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/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: SonoBook Series Diagnostic Ultrasound System

Transducer: L12M-V

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 ^[1] (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

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/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: SonoBook Series Diagnostic Ultrasound System

Transducer: L10i-V

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)	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

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/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: SonoBook Series Diagnostic Ultrasound System

Transducer: R7-V

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	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/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/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: SonoBook Series Diagnostic Ultrasound System

Transducer: L8M5-V

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 ^[1] (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

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/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: SonoBook Series Diagnostic Ultrasound System

Transducer: L18-V

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 ^[1] (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

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/4D
4. Elastography
5. Includes guidance of biopsy (2D)
6. Fusion Harmonic Imaging
7. TDI

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(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: SonoBook Series Diagnostic Ultrasound System

Transducer: E6-V

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	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/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/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: SonoBook Series Diagnostic Ultrasound System

Transducer: E7W-V

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	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/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/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) _____

Transducer: E7MW-V

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	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/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/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: SonoBook Series Diagnostic Ultrasound System
 Transducer: V6E-V

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	3,4,5,6
	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/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/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: SonoBook Series Diagnostic Ultrasound System

Transducer: MC3-V

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 ^[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Other (Urology)	N	N	N		N	N	N	4,5,6
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/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/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: SonoBook Series Diagnostic Ultrasound System

Transducer: MC6-V

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 ^[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Other (Urology)	N	N	N		N	N	N	4,5,6
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/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/4D

4. Elastography

5. Includes guidance of biopsy (2D)

6. Fusion Harmonic Imaging

7. TDI

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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: SonoBook Series Diagnostic Ultrasound System

Transducer: P3T-V

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	6
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ ^[1] (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/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/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: SonoBook Series Diagnostic Ultrasound System

Transducer: P5-V

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	6
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ ^[1] (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/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/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: SonoBook Series Diagnostic Ultrasound System

Transducer: CW2-V

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 (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/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: SonoBook Series Diagnostic Ultrasound System

Transducer: VC4-V

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 ^[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Other (Urology)	N	N	N		N	N	N	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/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/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: SonoBook Series Diagnostic Ultrasound System

Transducer: T5-V

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 (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/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/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) _____

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: December 29, 2016

2. Device :

Trade Name: SonoBook 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):

Q Series Diagnostic Ultrasound System
510(k) Number: K153085

4. Device Description:

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

Laboratory tests were conducted to verify that the SonoBook Series Diagnostic Ultrasound System met all design specifications and the SonoBook Series Diagnostic Ultrasound System conformed to applicable medical device standards.

The SonoBook Series Diagnostic Ultrasound System has been designed and manufactured to meet the following standards:

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

	Predicate Device	Submission Device	Remark
Product Name (K number)	Q Series Diagnostic Ultrasound System K150861	SonoBook Series Diagnostic Ultrasound System - 510(k) TBD	
Indications for Use	Fetal Abdominal Pediatric Small Organ (breast, thyroid, testes) Neonatal Cephalic ,Adult Cephalic Trans-rectal Trans-vaginal Musculo-skeletal(	Fetal Abdominal Pediatric Small Organ (breast, thyroid, testes) Neonatal Cephalic, Adult Cephalic Trans-rectal Trans-vaginal Musculo-skeletal(Conventional,	Same

	Predicate Device	Submission Device	
Product Name (K number)	Q Series Diagnostic Ultrasound System K150861	SonoBook Series Diagnostic Ultrasound System - 510(k) TBD	Remark
	Conventional, Superficial) Cardiac(adult ,pediatric) Peripheral Vascular Urology Transesophageal	Superficial) Cardiac(adult ,pediatric) Peripheral Vascular Urology Transesophageal	
Design	Based on an embedded WINDOWS operating system. 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	Based on an embedded WINDOWS operating system. 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
Operation Controls	TGC 8 slider	TGC 8 slider	Same
	Depth Range: 0 to 30 cm	Depth Range: 0 to 30 cm	Same
	256 shades of gray	256 shades of gray	Same
	B Dynamic range control: 30- 180 dB, 5/step	B Dynamic range control: 60- 165 dB, 7/step	SE Analysis 1
	Gain:0-255	Gain:0-255	Same
	Focal Number: adjustable	Focal Number: adjustable	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:4 steps	SE Analysis 1
	Color Baseline: 16 steps	Color Baseline: 7 steps	SE Analysis 1
	Color Maps: 21 maps	Color Maps: 11 maps	SE Analysis 1
	Color Invert: on/off	Color Invert: on/off	Same
	PW sweeping speed: 6 steps	PW sweeping speed: 3 steps	SE Analysis 1
	PW Wall Filter: 7 steps	PW Wall Filter: 4 steps	SE Analysis 1
	PW sample volume: 0.5- 30mm (PW only), 13 steps	PW sample volume: 1-8mm (PW only), 8 steps	SE Analysis 1
	PW angle correction:- 89~89degrees,1/step	PW angle correction:- 80~80degrees,5/step	SE Analysis 1
	Baseline: 8steps	Baseline: 7steps	SE Analysis 1
	Cine control: step, play backward, play continuously	Cine control: step, play backward, play continuously	Same

	Predicate Device	Submission Device	
Product Name (K number)	Q Series Diagnostic Ultrasound System K150861	SonoBook Series Diagnostic Ultrasound System - 510(k) TBD	Remark
	Doppler Auto Trace	Doppler Auto Trace	Same
	Freeze control: Toggling freeze key	Freeze control: Toggling freeze key	Same
Safety Standards Compliance	IEC60601-1 IEC60601-1-2 IEC60601-2-37 ISO 10993-1 ISO 10993-5 ISO 10993-10 AIUM/ NEMA UD2 AIUM/ NEMA UD3	IEC60601-1 IEC60601-1-2 IEC60601-2-37 ISO 10993-1 ISO 10993-5 ISO 10993-10 AIUM/ NEMA UD2 AIUM/ NEMA UD3	Same
Operation Mode	B, THI,B/M, M, Color M, Free Steering M ,CFM, PW,PDI,DPD,CW, 3D/ 4D , TDI, Elastography, Curved Panoramic, Trapezoidal image, Compound Imaging	B, FHI,B/M, M, Color M, Free Steering M, CFM, PW, PDI, DPD, CW, 3D/4D, Elastography, TDI, Curved Panoramic,Trapezoidal image, Compound Imaging	Same
Display Modes	B, 2B,4B, B/M ,M,TDI,3D/4D, B/BC,B/M, B+Color M, B+PW, B+CFM, B+PDI/DPD, B+CFM+PW/CW,B+ PD/DPD+PW/CW	B, 2B,4B, B/M ,M,TDI, 3D/4D,CW B/BC,B/M, B+Color M, B+PW/CW, B+CFM, B+PDI/DPD, B+CFM+PW/CW,B+ PDI/DPD+PW	Same
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 Curve; 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 Curve; Focus position; Thumbnail; Imaging parameters; Dynamic Trackball indices	Same
Display Monitor	15"high-resolution color LCD monitor	15" high-resolution color LCD monitor	Same

	Predicate Device	Submission Device	
Product Name (K number)	Q Series Diagnostic Ultrasound System K150861	SonoBook Series Diagnostic Ultrasound System - 510(k) TBD	Remark
Measurements	2D mode: 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; 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 , 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, S/D, Volume Flow;	SE Analysis2
Transducer Types & Connectors	Convex Array, Phased Array, Linear Array, Volume probe 2ports	Convex Array, Phased Array, Linear Array, Volume probe 1ports	SE Analysis3
Acoustic Output	Derated ISPTA: 720mW/cm ² maximum. TIS/TIB/TIC: 6.0 maximum, MI: 1.9 maximum, Derated ISPPA: 190 W/cm ² maximum	Derated ISPTA: 720mW/cm ² maximum. TIS/TIB/TIC: 6.0 maximum, MI: 1.9 maximum, Derated ISPPA: 190 W/cm ² maximum	Same
Power Supply	Voltage: 100-240V~ Frequency:50-60Hz Power Consumption: 300VA Max.	Voltage: 100-240V~ Frequency:50-60Hz Power Consumption: 300VA Max.	Same

SE Analysis1:

Operation Controls, compared with the predicate device, the subject device employs the same operation controls design and has some differences in value range or setting. 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 Analysis2:

Compared with the predicate device, the subject device has some differences in Measurement Items. But all of them for the subject device include the clinical basic items, and fall within these for the predicate device; all of them meet the clinical use and no new risk is raised.

SE Analysis3:

The probe connectors of the proposed device and the predicate device are 1 ports and 2 ports, but both them comply with the requirements of IEC60601-1. Therefore they can be considered Substantially Equivalent in safety, and no new risk is raised, so the SE is not affected. Therefore, probe connectors can be considered Substantially Equivalent in safety.

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 SonoBook Series Diagnostic Ultrasound System is substantially equivalent to the predicate devices with regard to safety and effectiveness.