Shenzhen Wisonic Medical Technology Co., Ltd.
% Jiang Xiaosan
Regulatory Engineer
1st and 5th Floor,No. 6 Building, Pingshan Technology Park,
Taoyuan Street, Nanshan
Shenzhen, Guang Dong 518055
CHINA

May 9, 2018

Re: K180461
Trade/Device Name: Navi e/Navi s/Navi X Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, ITX, IYO
Dated: February 7, 2018
Received: February 20, 2018

Dear Jiang Xiaosan:

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.

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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180461

Device Name
Navi e/Navi s/Navi X Diagnostic Ultrasound System

Indications for Use *(Describe)*
The Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in gynecology, obstetric, abdominal, pediatric, small parts (breast, testes,thyroid,etc.),neonatal cephalic, transcranial, cardiac, transvaginal, peripheral vascular, urology, orthopedic, and musculoskeletal (conventional and superficial) exams.

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 Format

System: Navi s/e/X Diagnostic Ultrasound System

Probe: N/A

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 (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1,4
	Abdominal	N	N	N	N	N	N	N	Note 1,4
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N	N	N	N	N	Note 1,4
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,4
	Neonatal Cephalic	N	N	N	N	N	N	N	Note 1,4
	Adult Cephalic	N	N	N	N	N	N	N	Note 1,4
	Trans-rectal	N	N	N		N	N	N	Note 1,4
	Trans-vaginal	N	N	N		N	N	N	Note 1,4
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,4
	Intravascular								
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	Note 1,4
	Cardiac Pediatric	N	N	N	N	N	N	N	Note 1,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,4
	Other (Specify***)	N	N	N		N	N	N	Note 1,4

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

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note2: 4D(Real-time 3D)
Note3: TDI
Note4: Biopsy Guidance
Note5: Anatomic M
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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

System: Navi s/e/X Diagnostic Ultrasound System

Probe: C5-1B

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 (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 4
	Abdominal	N	N	N		N	N	N	Note 1, 4
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1, 4
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 4
	Other (Specify***)								

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

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note2: 4D(Real-time 3D)
Note3: TDI
Note4: Biopsy Guidance
Note5: Anatomic M
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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

System: Navi s/e/X Diagnostic Ultrasound System

Probe: L15-4B

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 (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	N	Note 1, 4
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1, 4
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1, 4
	Neonatal Cephalic	N	N	N		N	N	N	Note 1, 4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1, 4
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1, 4
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 4
	Other (Specify***)								

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

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note1: Tissue Harmonic Imaging. The feature does not use contrast agents.
Note2: 4D(Real-time 3D)
Note3: TDI
Note4: Biopsy Guidance
Note5: Anatomic M
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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

System: Navi s/e/X Diagnostic Ultrasound System

Probe: P4-1

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 (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N	N	N	N	N	Note 1,4
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N	N	N	N	N	Note 1,4
	Small Organ (Specify**)								
	Neonatal Cephalic	N	N	N	N	N	N	N	Note 1,4
	Adult Cephalic	N	N	N	N	N	N	N	Note 1,4
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	Note 1,4
	Cardiac Pediatric	N	N	N	N	N	N	N	Note 1,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

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

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.
**Small organ-breast, thyroid, testes.
***Other use includes Urology.
Note1: Tissue Harmonic Imaging. The feature does not use contrast agents.
Note2: 4D(Real-time 3D)
Note3: TDI
Note4: Biopsy Guidance
Note5: Anatomic M
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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

System: Navi s/e/X Diagnostic Ultrasound System

Probe: LH15-6

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 (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	N	Note 1,4
	Intra-operative (Specify*)	N	N	N		N	N	N	Note 1,4
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1,4
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,4
	Neonatal Cephalic	N	N	N		N	N	N	Note 1,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,4
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,4
	Other (Specify***)								

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

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes.
***Other use includes Urology.
Note1: Tissue Harmonic Imaging. The feature does not use contrast agents.
Note2: 4D(Real-time 3D)
Note3: TDI
Note4: Biopsy Guidance
Note5: Anatomic M
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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

System: Navi s/e/X Diagnostic Ultrasound System

Probe: EV10-4

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 (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1,4
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	N	Note 1,4
	Trans-vaginal	N	N	N		N	N	N	Note 1,4
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)	N	N	N		N	N	N	Note 1,4

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

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.
**Small organ-breast, thyroid, testes.
***Other use includes Urology.
Note1: Tissue Harmonic Imaging. The feature does not use contrast agents.
Note2: 4D(Real-time 3D)
Note3: TDI
Note4: Biopsy Guidance
Note5: Anatomic M
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)
Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

System: Navi s/e/X Diagnostic Ultrasound System

Probe: C7-2

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 (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 4
	Abdominal	N	N	N		N	N	N	Note 1, 4
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1, 4
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 4
	Other (Specify***)								

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

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note2: 4D(Real-time 3D)
Note3: TDI
Note4: Biopsy Guidance
Note5: Anatomic M
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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

System: Navi s/e/X Diagnostic Ultrasound System

Probe: L15-4NB

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 (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	N	Note 1, 4
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1, 4
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1, 4
	Neonatal Cephalic	N	N	N		N	N	N	Note 1, 4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1, 4
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1, 4
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 4
	Other (Specify***)								

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

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note1: Tissue Harmonic Imaging. The feature does not use contrast agents.
Note2: 4D(Real-time 3D)
Note3: TDI
Note4: Biopsy Guidance
Note5: Anatomic M
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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

System: Navi s/e/X Diagnostic Ultrasound System

Probe: C8-3

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 (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 4
	Abdominal	N	N	N		N	N	N	Note 1, 4
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1, 4
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 4
	Other (Specify***)								

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

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note2: 4D(Real-time 3D)
Note3: TDI
Note4: Biopsy Guidance
Note5: Anatomic M
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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

510(k) Summary

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

1. SUBMITTER

Shenzhen Wisonic Medical Technology Co., LTD.
1st and 5th Floor, NO.6 Building, Pingshan Technology Park, Taoyuan Street,
Nanshan, Shenzhen. Guangdong, 518055, P.R. CHINA
Tel: (+86) 755 86007788
Fax: (+86) 755 86007799

Contact Person:	Xiaosan Jiang Regulatory Engineer Shenzhen Wisonic Medical Technology Co., LTD. Tel: (+86)-755 86007788-8003 Fax: (+86)-755 86007799
Date prepared	Feb 7, 2018

2. DEVICE

Device Name:	Navi e/ Navi s/ Navi X Diagnostic Ultrasound System
Common/Usual Name:	Diagnostic Ultrasound System
Regulation number	21 CFR 892.1550
Regulation Name	Ultrasonic pulsed doppler imaging system
Regulation Class:	II
Product Code:	IYN, ITX, IYO
Classification Name	System, Imaging, Pulsed Doppler, Ultrasonic
Model	Navi e/ Navi s/ Navi X

3. PREDICATE/ REFERENCE DEVICE

Predicate device:K143475, TE7 Diagnostic Ultrasound System
Reference device 1:K131690, M7/M7T Diagnostic Ultrasound System

Reference device 2:K140254,EZONO 4000 Ultrasound System

Reference device 3:K161999,AIXPLORER® Ultrasound Diagnostic System

The predicate device and reference devices have not been subject to a design-related recall.

4. DEVICE DESCRIPTION

The Navi e/ Navi s/Navi X Diagnostic Ultrasound System is a touch screen controlled ultrasonic system. Its function is to acquire and display ultrasound data in B-Mode, M-Mode, Color-Mode, Power (Dirpower)-Mode, PW-Mode, CW-mode, and the combined mode. The system can also measure anatomical structures and offer software analysis packages performance to provide information based on which the competent health care professionals can make the diagnosis.

The Navi e/ Navi s/Navi X Diagnostic Ultrasound System consists of the main unit named Navi series, ultrasound probes, power adapter, connecting cable, probe extender, needle-guided bracket, batteries, mobile trolley, ECG module and batteries

Three models for the main units are included in this submission, that is Navi s, Navi e and Navi X. Eight different models of probes are available for the Navi series.

5. INDICATIONS FOR USE

The Navi e/ Navi s/Navi X ultrasonic diagnostic system is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in gynecology, obstetric, abdominal, pediatric, small parts (breast, testes, thyroid, etc.), neonatal cephalic, transcranial, cardiac, transvaginal, peripheral vascular, urology, orthopedic, and musculoskeletal (conventional and superficial) exams.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Navi e/s/X ultrasonic diagnostic system is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Control Number
Predicate	Mindray	TE7	K143472
Reference device 1	EZONO AG	EZONO 4000	K140254
Reference device 2	Mindray	M7/M7T	K100830
Reference device 3	Supersonic	Aixplorer	K161999

Compared to the predicate devices TE7 (K143472),

The proposed device has the same intended uses, except for trans-esoph (Cardiac). The Navi e/Navi s/Navi X do not support trans-esoph (Cardiac) application. The intended use of Navi e/Navi s/Navi X is smaller than that of TE7.

The proposed device has the same structure. The clinical application is the same, and the performance is similar.

The proposed device has the same image scan mode, probe types and image parameters.

The proposed device has the same probe ports.

The proposed device has the same capability in term of measurements and calculation functions .

The proposed device has the same function, except for Needle Guide System(NGS), which detects the position and orientation of magnetized needles in the presence of the probe and displays this information relative to the ultrasound image. This function has similar operating principals and specifications as the reference device K140254.

This difference in technological characteristics do not raise different questions of safety and effectiveness as compared to the predicate device.

7. NON-CLINICAL DATA

The following non-clinical data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Double Electric Breast Pump was conducted in accordance with the International Standard ISO 10993-1:2009/(R)2013, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" as recognized by FDA. The biocompatible testing included the following tests:

- Cytotoxicity
- Sensitization
- Skin Irritation

The ultrasonic probes and glue of the Diagnostic Ultrasound System are considered to contact directly with human body for a duration of less than 24 hours. The test results of cytotoxicity, sensitization and skin irritation complied with ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity and ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. It demonstrates substantial equivalences to the predicate device.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Diagnostic Ultrasound System. The device complies with the IEC 60601-1:2012, standard for safety and the IEC 60601-1-2:2007, standard for EMC. It demonstrates substantial equivalences to the predicate device.

Performance testing

The Diagnostic Ultrasound System, was tested according to IEC 60601-2-37:2007, and met the requirements of IEC 60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment.

Performance testing was conducted on the Clover 50/Clover60/Clover70 Diagnostic Ultrasound System, to evaluate the clinic measurement accuracy and system sensitivity, and all of the tested parameters met the predefined acceptance criteria.

Acoustic output measurement and real time display function were evaluated in the Ultrasonic Diagnostic System, according to the standards NEMA UD 2:2004, Acoustic

Output Measurement Standard for Diagnostic Ultrasound Equipment, and NEMA UD 3:2004, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, respectively. All the device met the requirements.

The performance of the device was compared with the predicate devices, and it is concluded that the proposed device is substantially equivalent to the predicate device.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider. It demonstrates substantial equivalences to the predicate device.

Animal Study

The subject of this premarket submission, Navi e/Navi s/Navi X Diagnostic Ultrasound System, does not require animal studies to support substantial equivalence.

8. CLINICAL DATA

The subject of this premarket submission, Navi e/Navi s/Navi X Diagnostic Ultrasound System, did not require clinical studies to support substantial equivalence.

9. CONCLUSION

The differences between the Navi e/Navi s/Navi X Diagnostic Ultrasound System and its predicate device do not raise different questions of safety and effectiveness. The non-clinical data support the safety of the device and the performance testing report demonstrate that the Navi e/Navi s/Navi X Diagnostic Ultrasound System should perform as intended in the specified use conditions.

From the results of non-clinical data including the performance testing described, Shenzhen Wisonic concludes that the Navi e/Navi s/Navi X Diagnostic Ultrasound System is as safe and as effective as the predicate devices.