Shantou Institute of Ultrasonic Instruments Co., Ltd. (SIUI)
% Ms. Flower Cai
Liaison Manager
77 Jinsha Road
Shantou, Guangdong 515041
CHINA

December 7, 2017

Re: K173000
Trade/Device Name: Apogee 2100 Digital Color Doppler Ultrasound Imaging System
Apogee 2300 Digital Color Doppler Ultrasound Imaging System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: September 28, 2017
Received: October 2, 2017

Dear Ms. Cai:

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,

Michael D. O'Hara 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)*
K173000

Device Name
Apogee 2100 Digital Color Doppler Ultrasound Imaging System
Apogee 2300 Digital Color Doppler Ultrasound Imaging System

Indications for Use *(Describe)*
Diagnostic ultrasonic imaging for abdominal, pediatric, small organ, musculoskeletal, cardiac, peripheral vascular, trans-vaginal and trans-rectal applications in B-Mode (B, 2B, 4B), M-Mode, CFM, CPA, PWD, CWD, Combined (B, M, CFM, CPA, PWD, CWD, XBeam, Panoscope, and others (3D, 4D, Trapezoidal /Extended Sector Imaging, Elastography, Anatomical M-mode, TDI, MFI, ECG ,VS Flow, Color M and DICOM).

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.

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Diagnostic Ultrasound Indications for Use Form

3.1 System Indications for Use Form

System: Apogee 2100/ Apogee 2300

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	**N**	**N**	**N**		**N**		**N**
	Abdominal	**N**	**N**	**N**		**N**		**N**
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	**N**	**N**	**N**		**N**		**N**
	Small Organ (Specify)	**N**	**N**	**N**		**N**		**N**
	Neonatal Cephalic	**N**	**N**	**N**	**N**	**N**		**N**
	Adult Cephalic							
	Trans-rectal	**N**	**N**	**N**		**N**		**N**
	Trans-vaginal	**N**	**N**	**N**		**N**		**N**
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)	**N**	**N**	**N**		**N**		**N**
	Musculo-skeletal (**Superficial**)	**N**	**N**	**N**		**N**		**N**
	Intravascular							
	Other (Specify)	**N**	**N**	**N**		**N**		**N**
Cardiac	Cardiac Adult	**N**	**N**	**N**	**N**	**N**		**N**
	Cardiac Pediatric	**N**	**N**	**N**	**N**	**N**		**N**
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	**N**	**N**	**N**		**N**		**N**
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Other modes of operation include: CPA, 3-D Imaging, 4-D Imaging, Elastography, XBeam, Panoscope, Trapezoidal /Extended Sector Imaging, Anatomical M-mode, ECG,VS Flow, Color M,DICOM
Additional Comments: Other uses include: Gynecology, Prostate, Urology, Kidney, Uterus, Ovary
Small organs include: Thyroid, Testes, Breast

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

3.2 Transducer Indications for Use Form

Transducer: Convex Array C3LN

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	**N**	**N**	**N**		**N**		**N**
	Abdominal	**N**	**N**	**N**		**N**		**N**
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)	**N**	**N**	**N**		**N**		**N**
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Other modes of operation include: CPA, 3-D Imaging, XBeam, Panoscope, Trapezoidal / Extended Sector Imaging, Anatomical M-mode, ECG,VS Flow, Color M,DICOM
Additional Comments: Other uses include: Gynecology, Urology, Prostate, Kidney, Uterus, Ovary

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

3.3 Transducer Indications for Use Form

Transducer: Linear Array L8LN

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	**N**	**N**	**N**		**N**		**N**
	Small Organ (Specify)	**N**	**N**	**N**		**N**		**N**
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)	**N**	**N**	**N**		**N**		**N**
	Musculo-skeletal (**Superficial**)	**N**	**N**	**N**		**N**		**N**
	Intravascular							
	Other (Specify)	**N**	**N**	**N**		**N**		**N**
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	**N**	**N**	**N**		**N**		
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Other modes of operation include: CPA, 3-D Imaging, Elastography, XBeam, Panoscope, Trapezoidal / Extended Sector Imaging, Anatomical M-mode, ECG,VS Flow, Color M,DICOM
Additional Comments: Small organs include: Thyroid, Testes, Breast

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

3.4 Transducer Indications for Use Form

Transducer: Convex Array C5LN

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	**N**	**N**	**N**		**N**		**N**
	Abdominal	**N**	**N**	**N**		**N**		**N**
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)	**N**	**N**	**N**		**N**		**N**
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Other modes include: CPA, 4-D Imaging, XBeam, Panoscope, Trapezoidal /Extended Sector Imaging, Anatomical M-mode, ECG,DICOM
Additional Comments: Other uses include: Gynecology, Urology, Prostate, Kidney, Uterus, Ovary

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

3.5 Transducer Indications for Use Form

Transducer: Phased Array P3FN

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic	**N**	**N**	**N**	**N**	**N**		**N**
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	**N**	**N**	**N**	**N**	**N**		**N**
	Cardiac Pediatric	**N**	**N**	**N**	**N**	**N**		**N**
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Other modes of operation include: CPA, Trapezoidal /Extended Sector Imaging Anatomical M-mode, TDI, ECG,VS Flow, Color M,DICOM

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

3.6 Transducer Indications for Use Form

Transducer: Endocavity V6LN

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	**N**	**N**	**N**		**N**		**N**
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	**N**	**N**	**N**		**N**		**N**
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)	**N**	**N**	**N**		**N**		**N**
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Other modes of operation include: CPA, 3-D Imaging, XBeam, Panoscope, Trapezoidal /Extended Sector Imaging, Anatomical M-mode, ECG,VS Flow, Color M,DICOM
Additional Comments: Other uses include: Gynecology, Urology, Uterus, Ovary

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

3.7 Transducer Indications for Use Form

Transducer: Endocavity Biplane ECBN

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	**N**	**N**	**N**		**N**		**N**
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	**N**	**N**	**N**		**N**		**N**
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)	**N**	**N**	**N**		**N**		**N**
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Other modes of operation include: CPA, 3-D Imaging, XBeam, Panoscope, Trapezoidal / Extended Sector Imaging, Anatomical M-mode, ECG,VS Flow, Color M,DICOM
Additional Comments: Other uses include: Gynecology, Uterus, Ovary

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

3.8 Transducer Indications for Use Form

Transducer: Linear Array L10LN

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	**N**	**N**	**N**		**N**		
	Small Organ (Specify)	**N**	**N**	**N**		**N**		**N**
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)	**N**	**N**	**N**		**N**		**N**
	Musculo-skeletal (**Superficial**)	**N**	**N**	**N**		**N**		**N**
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	**N**	**N**	**N**		**N**		
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Other modes of operation include: CPA, 3-D Imaging, Elastography, XBeam, Panoscope, Trapezoidal /Extended Sector Imaging, Anatomical M-mode, ECG,VS Flow, Color M,DICOM
Small organs include: Thyroid, Testes, Breast

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

3.9 Transducer Indications for Use Form

Transducer: Endocavity Linear U5LN

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	**N**	**N**	**N**		**N**		**N**
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)	**N**	**N**	**N**		**N**		**N**
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Other modes of operation include: CPA, 3-D Imaging, XBeam, Panoscope, Trapezoidal /Extended Sector Imaging, Anatomical M-mode, ECG,VS Flow, Color M,DICOM
Additional Comments: Other uses include: Urology,

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

3.10 Transducer Indications for Use Form

Transducer: Convex Array C6LN

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	**N**	**N**	**N**		**N**		**N**
	Abdominal	**N**	**N**	**N**		**N**		**N**
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic	**N**	**N**	**N**		**N**		**N**
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	**N**	**N**	**N**		**N**		**N**
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Other modes of operation include: CPA, 3-D Imaging, XBeam, Panoscope, Trapezoidal /Extended Sector Imaging, Anatomical M-mode, ECG,VS Flow, Color M,DICOM

Prescription Use (Per 21 CFR 801.109)

510(k) Summary

This summary of 510(k) safety and effectiveness information is provided in accordance with the requirements of SMDA 1990 and 21 CFR 807.92(c).

The assigned 510(k) number is: K173000

1. 510(k) Owner:

Shantou Institute of Ultrasonic Instruments Co., Ltd. (SIUI)

77 Jinsha Road, Shantou, Guangdong 515041, China

Tel: 86-754-88250150 Fax: 86-754-88251499

Contact Person:

Flower Cai

Shantou Institute of Ultrasonic Instruments Co., Ltd.

77 Jinsha Road, Shantou, Guangdong 515041, China

Date Prepared: September 25, 2017

2. Device/Trade Name:

Apogee 2100 Digital Color Doppler Ultrasound Imaging System
Apogee 2300 Digital Color Doppler Ultrasound Imaging System

Classification Name:

Regulatory Class: II

Ultrasonic Pulsed Doppler Imaging System	90-IYN	(per 21 CFR 892.1550)
Ultrasonic Pulsed Echo Imaging System	90-IYO	(per 21 CFR 892.1560)
Diagnostic Ultrasound Transducer	90-ITX	(per 21 CFR 892.1570)

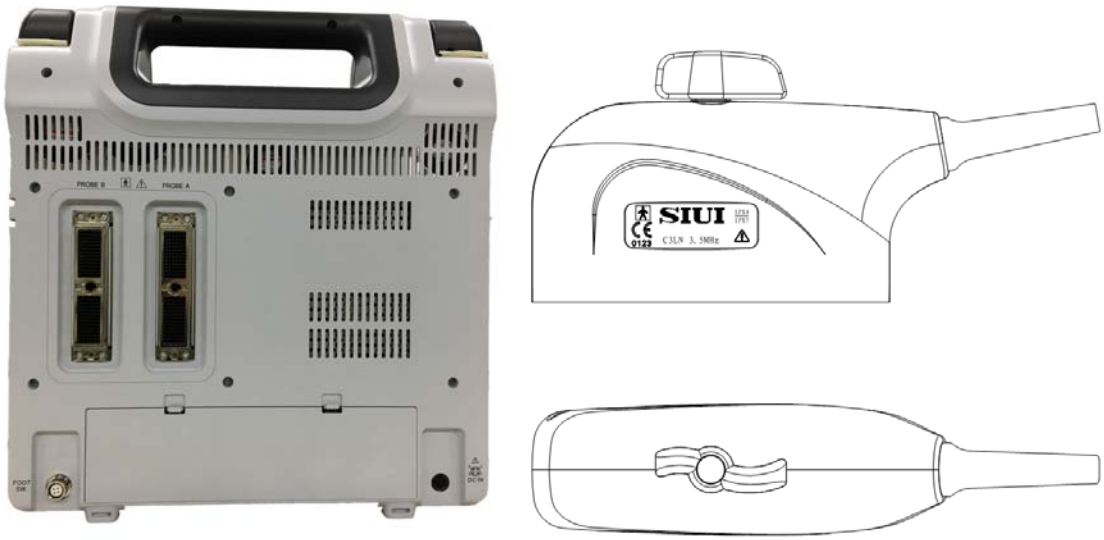
3. Device Description:

The SIUI Apogee 2100/ Apogee 2300 is a Digital Ultrasound Imaging System capable of the following operating modes: B-Mode (B, 2B, 4B), M-Mode, CFM, CPA, PWD, CWD, Combined (B, M, CFM, CPA, PWD, CWD, XBeam, Panoscope), others (3D, 4D, Trapezoidal /Extended Sector Imaging, Elastography, Anatomical M-mode, TDI, MFI, ECG, VS Flow, Color M, DICOM).

The system is designed for use in linear, convex, phased array and 3D scanning modes and supports linear, convex, phased array, 3D and endocavity (trans-vaginal and trans-rectal) transducers. The system has cine review, image zoom, measurements and calculations, image storage and review, printing and recording capabilities.

Apogee 2100 vs. Apogee 2300:
The Apogee 2100 and Apogee 2300 are the same in their working principle and internal modules.
Here are their main differences:

- The colors of rear panels are different.
- The structures of probe connectors are different, and the cosmetic designs of the supporting probe matching boxes are different. However, the working principle and the implementation principle of the probes are the same.



Figures of Apogee 2100 rear panel and supporting probe cosmetic design

Figures of Apogee 2300 rear panel and supporting probe cosmetic design

- Subject to different market positioning, the Apogee 2100 / Apogee 2300 have different functional configurations. See the table below for details:

Functional Configuration	Apogee 2100	Apogee 2300
B	√	√
2B	√	√
4B	√	√
B/M	√	√
M	√	√
PW	√	√
B+CFM	√	√
B+CPA	√	√
B+PW	√	√
Triplex (B+CFM+PW, B+CPA+PW)	√	√
Trapezoidal /Extended Sector Imaging	√	√
XBeam	√	√
Panoscope	√	√
Anatomical M-mode	√	√
CW	√	○
3D	√	√
4D	√	√
TDI	○	○
Elastography	○	○
MFI	√	√
ECG	○	○
Color M	○	○
VS Flow	√	√
B Flow	√	√

Functional Configuration	Apogee 2100	Apogee 2300
HPRF	√	√
DICOM	√	√

Notes: √ for standard configuration, and ○ for optional purchase.

4. Indications For Use:

Diagnostic ultrasonic imaging for abdominal, pediatric, small organ, musculoskeletal, cardiac, peripheral vascular, trans-vaginal and trans-rectal applications in B-Mode (B, 2B, 4B), M-Mode, CFM, CPA, PWD, CWD, Combined (B, M, CFM, CPA, PWD, CWD, XBeam, Panoscope, and others (3D, 4D, Trapezoidal /Extended Sector Imaging, Elastography, Anatomical M-mode, TDI, MFI, ECG ,VS Flow, Color M and DICOM).

Comparison to Predicate Devices:

The Apogee 2100/ Apogee 2300 have three more imaging functions than the predicate SIUI Apogee 5500, namely VS Flow, Color M and DICOM.

All the Indications for Use of the Apogee 2100/ Apogee 2300 are included in the indications for use of predicate SIUI Apogee 1200.

5. Legally Marketed Predicate Device:

The Apogee 2100/ Apogee 2300 Digital Color Doppler Ultrasound Imaging Systems are multi-purpose diagnostic ultrasound systems with accessories and proprietary software, and are substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Control Number
1	SIUI	Apogee 1200 Digital Color Doppler Ultrasound Imaging System	K113613
2	SIUI	Apogee 5500 Digital Color Doppler Ultrasound Imaging System	K160853

Compared to the predicate devices SIUI Apogee 1200 (K113613**):**

The Apogee 2100/ Apogee 2300 mainly have cosmetic changes based on SIUI Apogee 1200 (K113613), with additional new features and new configurable transducers.

1) In cosmetic design, the Apogee 2300 is close to the Apogee 1200, except for changes

in some structure of the upper part of the machine and some adjustment on the control panel. In the overall structure, the control panels of the Apogee 2300 and Apogee 2100 are modified based on the Apogee 1200. Some functions achieved by toggle switches are changed to other knobs or menu operations through software control changes, but the overall control interface and protocol is not changed substantially. The display structure is modified that allows the display rotated up and down 35 degrees, which enhances the user experience and makes full use of structural space, making the system lighter and more compact.

Subject to cosmetic changes, the PCBAs in the system are adjusted in their size and layout, while the overall circuit principle is not changed. The Apogee 2100 /Apogee2300 and Apogee 1200 use the same PC module, digital signal processing module, and ultrasound front-end module.

With the changes in system cosmetic design, the cosmetic design of the connectors between probes and main unit is modified. To differentiate marketing needs, the cosmetic design of connector and match box is modified.

2) In new features, the Apogee 2100/ Apogee2300 have additional 4D, Trapezoidal /Extended Sector Imaging, Elastography, Anatomical M-mode, TDI, MFI, ECG,VS Flow and Color M, which are also available in Apogee 5500 (K160853), but the same in ultrasound diagnostic functions, imaging modes, measurement and calculation function, file storage management and compatible peripheral devices.
3) In probe configuration, due to cosmetic changes in connector and match box in the Apogee 2100 / Apogee 2300, the probe models are changed, and some additional transducers L10LN, C6LN, U5LN are configured (identical to Apogee 5500 (K160853)), and the range of application includes 5 additional exams Neonatal Cephalic, Trans-vaginal and Trans-rectal, Gynecology and Urology (identical to Apogee 5500 (K160853)).
4) The Apogee 2100/ Apogee 2300 are similar in technological characteristics to the SIUI Apogee 1200(K113613) .

Compared to the predicate devices Apogee 5500 (K160853):

For the technical specifications and transducers on the SIUI Apogee 2100/ Apogee 2300, the claim of substantial equivalence to devices currently having FDA 510(k) clearance is Apogee 5500 (K160853).

The Apogee 2100/ Apogee 2300 are similar in technological characteristics to the Apogee 5500.

1) The Apogee 2100/ Apogee 2300 and the Apogee 5500 have similar imaging modes.
2) The Apogee 2100/ Apogee 2300 and the Apogee 5500 have similar diagnostic ultrasound applications
3) The transducers of Apogee 2100/ Apogee 2300 and the Apogee 5500 have similar technical parameters and hardware implementation principle.
4) The Apogee 2100/ Apogee 2300 have similar diagnostic ultrasound applications as Apogee 5500.

6. Safety Considerations:

The Apogee 2100/ Apogee 2300 Digital Color Doppler Ultrasound Imaging System has been tested per the FDA Guidance document “Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers” issued in September 2008. The acoustic output is measured and calculated per NEMA UD 2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment: 2004. The device conforms to applicable medical device safety standards, such as IEC 60601-1, ISO10993-5, ISO 10993-10, and IEC 60601-1-2.

7. Conclusion:

The conclusions drawn from testing of the Apogee 2100/ Apogee 2300 Digital Color Doppler Ultrasound Imaging System demonstrates that the device is as safe and effective as the legally marketed predicate devices.