



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

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

June 27, 2016

Re: K160853

Trade/Device Name: Apogee 5500 Digital Color Doppler Ultrasound Imaging System
Apogee 5300 Digital Color Doppler Ultrasound Imaging System
Apogee 5800 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: March 29, 2016

Received: April 4, 2016

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. 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 black ink that reads "Robert Ochs". The signature is written in a cursive style with a clear, legible font.

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)

K160853

Device Name

Apogee 5500 Digital Color Doppler Ultrasound Imaging System

Apogee 5300 Digital Color Doppler Ultrasound Imaging System

Apogee 5800 Digital Color Doppler Ultrasound Imaging System

Indications for Use (Describe)

The device is intended for use by a qualified physician for ultrasound evaluation of Fetal, Abdominal, Pediatric, Small Organ (Thyroid, Testes, Breast), Neonatal Cephalic, Musculoskeletal (Conventional and Superficial), Cardiac (Adult and Pediatric), Peripheral Vascular, Trans-vaginal, Trans-rectal, Obstetrics/ Gynecology and Urology applications.

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 Form

3.1 System Indications for Use Form

System: Apogee 5500/ Apogee 5300/ Apogee 5800

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

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 C3LC

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, Elastography, XBeam, Panoscope, Trapezoidal / Extended Sector Imaging, Anatomical M-mode, ECG

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 L8LC

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

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 C5LF

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	
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, 3-D Imaging, 4-D Imaging, Elastography, XBeam, Panoscope, Trapezoidal /Extended Sector Imaging, Anatomical M-mode, ECG

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 P3FC

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, Elastography, XBeam, Trapezoidal /Extended Sector Imaging Anatomical M-mode, TDI, ECG

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

3.6 Transducer Indications for Use Form

Transducer: Endocavity V6LC

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	N	N	N		N		N
	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, Elastography, XBeam, Panoscope, Trapezoidal /Extended Sector Imaging, Anatomical M-mode, ECG

Additional Comments: Other uses include: Gynecology, Urology, Prostate, Kidney, Uterus, Ovary

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

3.7 Transducer Indications for Use Form

Transducer: Endocavity Biplane ECBP

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		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, Elastography, XBeam, Panoscope, Trapezoidal / Extended Sector Imaging, Anatomical M-mode, ECG

Additional Comments: Other uses include: Urology, Prostate, Kidney, 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 L10LC

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

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 U5LC

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		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, Elastography, XBeam, Panoscope, Trapezoidal /Extended Sector Imaging, Anatomical M-mode, ECG

Additional Comments: Other uses include: Gynecology, Urology, Prostate, Kidney, Uterus, Ovary

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

3.10 Transducer Indications for Use Form

Transducer: Convex Array C6LC

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)		N	N	N		N		N
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, Elastography, XBeam, Panoscope, Trapezoidal /Extended Sector Imaging, Anatomical M-mode, ECG

Additional Comments: Other uses include: Gynecology, Urology, Prostate, Kidney, Uterus, Ovary

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: K160853

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: March 24, 2016

2. Device/Trade Name:

Apogee 5500 Digital Color Doppler Ultrasound Imaging System
Apogee 5300 Digital Color Doppler Ultrasound Imaging System
Apogee 5800 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. Intended Use

The Apogee 5500/ Apogee 5300 /Apogee 5800 Digital Color Doppler Ultrasound Imaging System is intended for use by a qualified physician for ultrasound evaluation of Fetal, Abdominal, Pediatric, Small Organ (Thyroid, Testes, Breast), Neonatal Cephalic, Musculoskeletal (Conventional and Superficial), Cardiac (Adult and Pediatric), Peripheral Vascular, Trans-vaginal, Trans-rectal, Obstetrics/ Gynecology and Urology applications.

4. Device Description

The SIUI Apogee 5500/ Apogee 5300 /Apogee 5800 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), and other(3D, 4D, Trapezoidal /Extended Sector Imaging, Elastography, Anatomical M-mode, TDI, MFI, ECG).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 5500 vs. Apogee 5300:

The cosmetic structure designs are the same, except for the color of some structures.

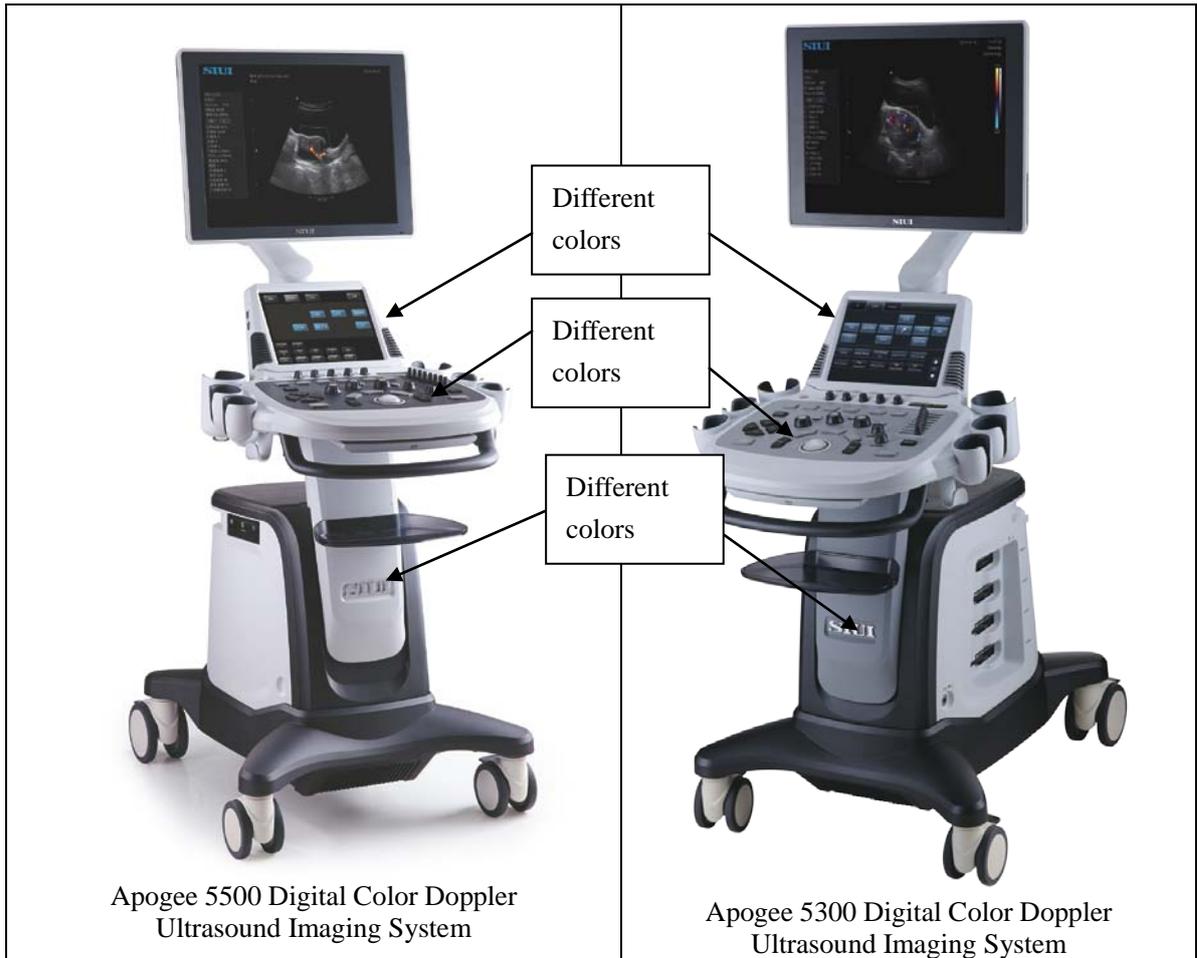
- Apogee 5500: the colors of speaker enclosure, keyboard cover board and elevation front and rear covers are dark gray, dark gray and white respectively.
- Apogee 5300: the colors of speaker enclosure, keyboard cover board and elevation front and rear covers are all light gray.

Apogee 5800 vs. Apogee 5500:

The cosmetic and structure designs are basically the same. Main differences:

- Apogee 5800: The cosmetic colors are pearl gray and white, and the dimensions are bigger. The overall shape is more plump and stable.
- Apogee 5500: more delicate and concise.

SIUI Apogee 5500/ Apogee 5300 /Apogee 5800
Digital Color Doppler Ultrasound Imaging System



Apogee 5800 Digital Color Doppler Ultrasound Imaging System

Comparison between: Apogee 5500, Apogee 5300 and Apogee 5800

- **Overall dimensions:** Subject to market positioning, the overall dimensions of Apogee 5500 and Apogee 5300 are smaller than Apogee 5800.
- **Chassis:** Subject to market positioning, the dimensions and structures of the chassis for Apogee 5500, Apogee 5300 and Apogee 5800 are different.
- **Internal module structure:** The internal modules are the same, and the main difference is in the expansion space. The Apogee 5800 has bigger size, enabling the placement of some accessories such as cables. Both the left and right sides of Apogee 5800 have the additional glove compartments.
- **Transducer socket position:** Apogee 5500 and Apogee 5300: on the right of the main unit, Apogee 5800: at the middle front of the main unit
- **Touch screen and monitor:** the same. They all use a 10.4-inch touch screen and a 19-inch monitor.
- **Call situations of some functional buttons on the control panels are modified.**
- **Functional Configuration:** Subject to market positioning, the Apogee 5500/ Apogee 5300/ Apogee 5800 have different functional configurations. See the details in the table below.

Functional Configuration	Apogee 5500	Apogee 5300	Apogee 5800
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	○	○	√

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

5. Legally Marketed Predicate Devices and Substantial Equivalence

The Apogee 5500/ Apogee 5300 /Apogee 5800 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) Number
1	SIUI	Apogee 3800 Digital Color Doppler Ultrasound Imaging System	K110841
2	SIEMENS	Acuson X700 Diagnostic Ultrasound System	K141846

5.1 Comparison of Indications for Use (IFU)

➤ IFU Statement

The subject device Apogee 5500/ Apogee 5300 /Apogee 5800 Digital Color Doppler Ultrasound Imaging System is intended for use by a qualified physician for ultrasound evaluation of Fetal, Abdominal, Pediatric, Small Organ (Thyroid, Testes, Breast), Neonatal Cephalic, Musculoskeletal (Conventional and Superficial), Cardiac (Adult and Pediatric), Peripheral Vascular, Trans-vaginal, Trans-rectal, Obstetrics/ Gynecology and Urology applications.

The predicate device Apogee 3800 Digital Color Doppler Ultrasound Imaging System (K110841) is intended for diagnostic ultrasonic imaging for abdominal, pediatric, small organ, musculo-skeletal, cardiac, peripheral vascular applications in B, M, PWD, Color Doppler and 3D imaging modes.

The predicate device SIEMENS Acuson X700 and X600 ultrasound imaging system

(K141846) “is intended for the following applications: Cardiac (Adult, Pediatric), Transesophageal (Cardiac), Intracardiac, Cerebrovascular, Peripheral Vessel, Abdominal, Renal, Fetal, Abdominal, Intra-operative, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Orthopedics, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Pelvic, Obstetrical, Gynecological and Urological applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the “ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging.

The Acuson Acunav and Soundstar Ultrasound Catheter are intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.”

➤ **Application**

The Apogee 5500/ Apogee 5300 /Apogee 5800 and the predicate Apogee 3800 (K110841) have the same applications except for 5 additional applications in the subject device: Neonatal Cephalic, Trans-vaginal, Trans-rectal, Gynecology and Urology. All the applications of the subject device Apogee 5500/ Apogee 5300 /Apogee 5800 are included in the applications of predicate Acuson X700 (K141846).

➤ **Display Mode**

The Apogee 5500/ Apogee 5300 /Apogee 5800 and the predicate Apogee 3800 (K110841) have the same technological characteristics, are comparable in key safety and effectiveness features, and have the same basic operating modes. All systems

transmit ultrasonic energy into patients, perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body.

Based on the same principle, the front-end transmit circuit controls are similar. After various post-processing for the acquired information data, the subject device Apogee 5500/ Apogee 5300 /Apogee 5800 has new imaging modes (XBeam, Panoscope, 4D, Trapezoidal / Extended Sector Imaging, Elastography, Anatomical M-mode, TDI, MFI), as well as the addition of ECG application circuit and function. The new imaging modes, which are similar to the predicate Acuson X700 (K141846), were tested and proved no impact on device safety and effectiveness.

➤ **Measurement and reporting**

The Apogee 5500/ Apogee 5300 /Apogee 5800 and the predicate Apogee 3800 (K110841) have the same measurement functions, measurement packages and reporting functions.

5.2 Comparison with the predicate device SIUI Apogee 3800 (K110841)

The Apogee 5500, Apogee 5300 and Apogee 5800 mainly have cosmetic changes based on SIUI Apogee 3800 (K110841), with additional new features and new configurable transducers.

- 1) In cosmetic design, the Apogee 5800 is close to the Apogee 3800, except for changes in some structure of the upper part of the machine and some adjustment on the control panel. Both Apogee 5500 and Apogee 5300 have slimmer cosmetic design to adapt to clinical application in smaller space, and the probe sockets are changed from the middle front to the right of the main unit, the locations of I/O panel, keyboard are changed accordingly, but the corresponding interfaces and circuit principle are not changed.
- 2) In new features, the Apogee 5500/ Apogee 5300/ Apogee 5800 have additional CWD, 3D, 4D, Trapezoidal /Extended Sector Imaging, Elastography, Anatomical M-mode, TDI, MFI and ECG (identical to Acuson X700 K141846).
- 3) In probe configuration, the Apogee 5500/ Apogee 5300/ Apogee 5800 have additional V6LC, ECBP, L10LC, C6LC, U5LC transducers (identical to Acuson X700 K141846),

and the range of application includes 5 additional exams Neonatal Cephalic, Trans-vaginal and Trans-rectal, Gynecology and Urology (identical to Acuson X700 K141846).

The SIUI Apogee 5500/ Apogee 5300/ Apogee 5800 are similar in technological characteristics to the SIUI Apogee 3800.

5.3 Comparison with the predicate device SIEMENS Acuson X700 (K141846)

For the technical specifications and transducers on the SIUI Apogee 5500/ Apogee 5300/ Apogee 5800, the claim of substantial equivalence to devices currently having FDA 510(k) clearance is Siemens Acuson X700 (K141846).

The SIUI Apogee 5500/ Apogee 5300/ Apogee 5800 is similar in technological characteristics to the Siemens Acuson X700.

- The SIUI Apogee 5500/ Apogee 5300/ Apogee 5800 and the Siemens Acuson X700 have similar imaging modes.
- The SIUI Apogee 5500/ Apogee 5300/ Apogee 5800 and the Siemens Acuson X700 have similar diagnostic ultrasound applications
- The transducers of SIUI Apogee 5500/ Apogee 5300/ Apogee 5800 and the Siemens Acuson X700 have similar technical parameters and hardware implementation principle.
- The SIUI Apogee 5500/ Apogee 5300/ Apogee 5800 have similar diagnostic ultrasound applications as Siemens Acuson X700.

6. Safety Considerations

The Apogee 5500/ Apogee 5300 /Apogee 5800 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 and ISO 10993-10.

7. Conclusion

The conclusions drawn from testing of the Apogee 5500/ Apogee 5300 /Apogee 5800 Digital Color Doppler Ultrasound Imaging System demonstrates that the device is as safe and effective as the legally marketed predicate devices.