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

August 18, 2021

Re: K210318
Trade/Device Name: Apogee 6500, Apogee 6300, Apogee 6200 Digital Color Doppler Ultrasound Imaging System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: July 8, 2021
Received: July 12, 2021

Dear Flower 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210318

Device Name
Apogee 6500 Digital Color Doppler Ultrasound Imaging System
Apogee 6300 Digital Color Doppler Ultrasound Imaging System
Apogee 6200 Digital Color Doppler Ultrasound Imaging System

Indications for Use *(Describe)*
The system is intended to be used by a trained/qualified physician in a hospital or clinical setting 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 in B-Mode (B, 2B, 4B), M-Mode, CFM, CPA, DPA, PWD, CWD, Combined (B, M, CFM, CPA, DPA, PWD, CWD, XBeam, Panoscope), and others (3D/4D, Trapezoidal /Extended Sector Imaging, Elastography, Anatomical M-mode, TDI, THI, MFI, ECG, VS Flow, Color M, 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.

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"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."

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: K210318

5.1 Submitter

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

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Contact Person: Flower Cai

Shantou Institute of Ultrasonic Instruments Co., Ltd.

77 Jinsha Road, Shantou, Guangdong 515041, China

Date Prepared: July 29, 2021

5.2 Device

Name of Device:

Apogee 6500 Digital Color Doppler Ultrasound Imaging System

Apogee 6300 Digital Color Doppler Ultrasound Imaging System

Apogee 6200 Digital Color Doppler Ultrasound Imaging System

510(k) submitter: SIUI

Classification Name:

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 ultrasonic transducer	90-ITX	(per 21 CFR 892.1570)

Regulatory Class: II

Product Code: IYN, IYO, ITX

5.3 Predicate Device

Name of Predicate Device:

Apogee 5500 Digital Color Doppler Ultrasound Imaging System (K160853)

510(k) holder: SIUI

Regulatory Class: II

Product Code: IYN, IYO, ITX

Classification Name:

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 ultrasonic transducer	90-ITX	(per 21 CFR 892.1570)

5.4 Device Description

5.4.1 Description

The SIUI Apogee 6500/ Apogee 6300/ Apogee 6200 Digital Color Ultrasound Imaging System capable of the following operating modes: B-Mode (B, 2B, 4B), M-Mode, CFM, CPA, DPA, PWD, CWD, Combined (B, M, CFM, CPA, DPA, PWD, CWD, XBeam, Panoscope), and others (3D/4D, Trapezoidal /Extended Sector Imaging, Elastography, Anatomical M-mode, TDI, THI, MFI, ECG, VS Flow, Color M, DICOM).

The system is designed for use in linear, convex, phased array scanning modes and supports linear, convex, phased array 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.

This system is a Track 3 device and the software used in Apogee 6500 / Apogee 6300/Apogee 6200 Digital Color Ultrasound Imaging System is Ultrasound Software

by SIUI and is based on the predicate device. The Level of Concern for the Ultrasound Software is Moderate.

5.4.2 Comparisons of Apogee 6500/Apogee 6300/Apogee 6200 devices

The Apogee 6500/ Apogee 6300/ Apogee 6200 use the same safe critical components, with the same circuit modules and working principles. The mechanical structure is designed for the market requirements of the devices according to the requirements of international general safety standard (IEC 60601-1). The hardware design is exactly the same for Apogee 6500/ Apogee 6300/ Apogee 6200. Subject to market positioning, the Apogee 6500/ Apogee 6300/Apogee 6200 have different software functional configurations. See the table below.

Product Model		Apogee 6500	Apogee 6300	Apogee 6200
Photo				
Functional configure-tion	XBeam	√	○	√
	Panoscope	√	√	○

Note: "√" means "standard configuration", "○" means "option configuration".

5.5 Indications for Use

The system is intended to be used by a trained/qualified physician in a hospital or clinical setting 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 in B-Mode (B, 2B, 4B), M-Mode, CFM, CPA, DPA, PWD, CWD, Combined (B, M, CFM, CPA, DPA, PWD, CWD, XBeam, Panoscope), and others (3D/4D, Trapezoidal /Extended Sector

Imaging, Elastography, Anatomical M-mode, TDI, THI, MFI, ECG, VS Flow, Color M, DICOM).

5.6 Comparison of Technological Characteristics with the Predicate Device

The Apogee 6500/Apogee 6300/Apogee 6200 Digital Color Doppler Ultrasound Imaging Systems are multi-purpose diagnostic ultrasound systems with accessories and proprietary software, and are substantially equivalent to the predicate device.

Type	Manufacturer	Device	510 (K) Number
Predicate device	SIUI	Apogee 5500 Digital Color Doppler Ultrasound Imaging System	K160853

For the intended use and technical specifications on the SIUI Apogee 6500/Apogee 6300/Apogee 6200, the claim of substantial equivalence to devices currently having FDA 510(k) clearance is SIUI Apogee 5500 Digital Color Doppler Ultrasound Imaging System (K160853).

For the transducers on the SIUI Apogee 6500/Apogee 6300/Apogee 6200, the claim of substantial equivalence to devices currently having FDA 510(k) clearance are SIUI Apogee 5500 Digital Color Doppler Ultrasound Imaging System (K160853).

Intended Use Comparison:

Compared with the predicate device Apogee 5500 (K160853), the Subject Devices have the same intended use.

Technical Characteristics Comparison:

The basic and key technical features of the subject Device are the same as the predicate device Apogee 5500 (K160853), including Operation Principle, Operation Controls, System Setup, Operation Modes, Measurement, Calculation and Report item Cine and File Management.

Acoustic power levels Comparison:

The Acoustic power levels of subject devices meet the limits of FDA same as the predicate device Apogee 5500 (K160853)

Materials of probes Comparison:

The materials of probes with subject device are same as the predicate device of Apogee 5500 (K160853).

Probes Comparison:

Apogee 6500/Apogee 6300/Apogee 6200 has similar probes as the predicated device

of Apogee 5500. The proposed Apogee 6500/Apogee 6300/Apogee 6200 adds two new transducers P5FC and V6LF to the system. Applications for these probes are within the indications for use of the predicate system Apogee 5500 (K160853). The application range and probe type of the P5FC probe is the same as that of the P3FC probe for the predicate device Apogee 5500 (K160853). The application range of the V6LF probe is the same as that of the V6LC probe for the predicate device Apogee 5500 (K160853).

Any differences between the predicate and the new device have no impact on safety or efficacy of the new device and do not raise any new potential or increased safety risks, and the new device is equivalent in performance to existing legally marketed devices.

5.7 Non-clinical Testing Summary

The Apogee 6500/ Apogee 6300/ Apogee 6200 Digital Color Doppler Ultrasound Imaging System comply with and/or were tested in accordance with the following FDA guidance and International Standards:

- IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests.
- IEC 60601-2-37:2007+A1:2015 Medical electrical equipment - Part 2-37:Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
- IEC 60601-2-25:2011 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
- ISO 14971:2019 Medical devices - Application of risk management to medical devices
- ISO 10993-1:2018 Biological evaluation of medical devices - Part1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices - Part5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10:Tests for

irritation and skin sensitization

- IEC 62304:2006+A1:2015 Medical device software – Software life cycle processes
- IEC 60601-1-6:2010+A1:2013 Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 62366-1:2015/COR1:2016 Medical devices – Part 1: Application of usability engineering to medical devices
- ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Marketing Clearance of Diagnostic Ultrasound Systems and Transducers

The subject device and the predicate device are comparable in terms of technical features, general functions, applications and intended uses. The test results showed compliance with the above standards. The non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate.

5.8 Clinical Testing

Clinical testing is not necessary for the Apogee 6500/ Apogee 6300/ Apogee 6200 Digital Color Doppler Ultrasound Imaging System in order to demonstrate substantial equivalence to the predicate device.

5.9 Conclusion

The subject device Apogee 6500/ Apogee 6300/ Apogee 6200 Digital Color Doppler Ultrasound Imaging System and the predicate device SIUI Apogee 5500 Digital Color Doppler Ultrasound Imaging System are comparable in terms of technical features, general functions, applications and indications for use.

Therefore, SIUI Apogee 6500/ Apogee 6300/ Apogee 6200 Digital Color Doppler Ultrasound Imaging System is substantially equivalent with respect to safety and effectiveness of the predicate device currently cleared for market.

Appendix

1. Acronyms and full names of imaging modes

Acronym	Full Name
CFM	Color Flow Map
CPA	Color Power Angio
DPA	Directional Power Angio
PWD	Pulsed Wave Doppler
CWD	Continuous Wave Doppler
THI	Tissue Harmonic Imaging
TDI	Tissue Doppler Imaging
MFI	Macro fidelity Imaging
VS Flow	Vector Space Flow

2. Equivalent Names of Subject Device

Equivalent Names of Subject Device	Apogee 6500 Digital Color Doppler Ultrasound Imaging System Apogee 6300 Digital Color Doppler Ultrasound Imaging System Apogee 6200 Digital Color Doppler Ultrasound Imaging System
	Apogee 6500/ Apogee 6300/ Apogee 6200 Digital Color Ultrasound Imaging System
	Apogee 6500/ Apogee 6300/ Apogee 6200
	Apogee 6500 series