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

August 19, 2021

Re: K210317
Trade/Device Name: Apogee 1000/ Apogee 1000Neo/ Apogee 1000Lite/ Apogee 1000Exp/ Apogee 1000B/W / Apogee 1U/ Apogee 1T/ Apogee 1G 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 19, 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)*
K210317

Device Name
Apogee 1000/ Apogee 1000Neo/ Apogee 1000Lite/ Apogee 1000Exp/ Apogee 1000B/W / Apogee 1U/ Apogee 1T/ Apogee 1G 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, 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.

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
PRAStaff@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."

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: K210317

5.1 Submitter

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: July 8, 2021

5.2 Device

Name of Device:

Apogee 1000/ Apogee 1000Neo/ Apogee 1000Lite/ Apogee 1000Exp/ Apogee 1000B/W/ Apogee 1U/ Apogee 1T/ Apogee 1G 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 2300 (K173000)

510(k) holder: 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

5.4 Device Description

5.4.1 Description

The SIUI Apogee 1000 series (Apogee 1000/ Apogee 1000Neo/ Apogee 1000Lite/ Apogee 1000Exp/ Apogee 1000B/W)/ Apogee 1 series (Apogee 1U/ Apogee 1T/ Apogee 1G) Digital Color Ultrasound Imaging System is 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, Trapezoidal /Extended Sector Imaging, Elastography, Anatomical M-mode, THI, TDI, DPA, 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 1000 series / Apogee 1 series 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 1000 series and Apogee 1 series devices

Except for the cosmetic color, the Apogee 1000 series and Apogee 1 series are completely the same. Subject to market positioning, the Apogee 1000 series/ Apogee 1 series have different functional configurations. See the table below.

Product Model		Apogee 1000 series					Apogee 1 series		
		Apogee 1000	Apogee 1000Neo	Apogee 1000Lite	Apogee 1000Exp	Apogee 1000B/W	Apogee 1U	Apogee 1T	Apogee 1G
Photo									
Functional configuration	Continuous Wave Doppler (CW)	○	○	○	√	○	√	○	√
	Trapezoidal/ Extended Sector Imaging	○	○	√	○	√	○	√	√
	Panoscope	○	√	○	○	√	√	√	√

Note: "○" means "option configuration", "√" means "standard 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, 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 1000 series/Apogee 1 series Digital Color Doppler Ultrasound Imaging Systems is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and are substantially equivalent to predicate devices.

The comparison between the overall specifications of predicate device (Apogee 2300 (K173000)) and the subject device (Apogee 1000/ Apogee 1000Neo/ Apogee 1000Lite/ Apogee 1000Exp/ Apogee 1000B/W/ Apogee 1U/ Apogee 1T/ Apogee 1G) are as follows:

1) Compared with the predicate device Apogee 2300, the subject devices have the same intended use.

2) In cosmetic design, the subject device has a smaller and lighter structure and appearance. 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 subject device and the predicate device use the same PC module, digital signal processing module, and ultrasound front-end module. Compared with the predicate device, the overall user interface of the subject device has not changed substantially, and the position of the probe connector is adjusted to the side of the device according to the cosmetic structure. As the overall structure dimensions become smaller, the number of probe connectors is less than that of the predicate device by 1. Furthermore, the structure of the monitor is optimized, not only maintaining the up and down invert function of the predicate device, but also to achieve a 90-degree rotation left and right, which improves the user experience.
3) In terms of functions, compared with the predicate device, the subject device lacks the 4D imaging mode, but both devices are the same in other ultrasonic diagnostic functions, imaging modes, file storage management, compatible peripherals, measurement and calculation functions.
4) In probe configuration, the subject device supports three new probe models: P5FN, ECBP-1 and ECBP-2. The application range of the P5FN probe (of the subject device) is the same as that of the P3FN probe for the predicate device, and the application range of the ECBP-1 and ECBP-2 probes (of the subject device) is the same as that of the ECBN probe for the predicate device.
5) The subject device is similar in technological characteristics to the predicate device.

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 1000 series/ Apogee 1 series 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 compatibility - Requirements and tests.
- IEC 60601-2-37:2007+AMD1:2015 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 device - 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+AMD1:2015 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 – 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 subject 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 1000 series/ Apogee 1 series Digital Color Doppler Ultrasound Imaging System in order to demonstrate substantial equivalence to the predicate device.

5.9 Conclusion

The subject device SIUI Apogee 1000 series (Apogee 1000/ Apogee 1000Neo/ Apogee 1000Lite/ Apogee 1000Exp/ Apogee 1000B/W)/ Apogee 1 series (Apogee 1U/ Apogee 1T/ Apogee 1G) Digital Color Doppler Ultrasound Imaging System and the predicate device SIUI Apogee 2300 Digital Color Doppler Ultrasound Imaging System are comparable in terms of technical features, general functions, applications and indications for use.

The nonclinical tests (discussed above) demonstrate that Apogee 1000 series (Apogee 1000/ Apogee 1000Neo/ Apogee 1000Lite/ Apogee 1000Exp/ Apogee 1000B/W)/ Apogee 1 series (Apogee 1U/ Apogee 1T/ Apogee 1G) Digital Color Doppler Ultrasound Imaging System performs as well as, and 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 1000/ Apogee 1000Neo/ Apogee 1000Lite/ Apogee 1000Exp/ Apogee 1000B/W/ Apogee 1U/ Apogee 1T/ Apogee 1G Digital Color Doppler Ultrasound Imaging System
	Apogee 1000 Digital Color Doppler Ultrasound Imaging System Apogee 1000Neo Digital Color Doppler Ultrasound Imaging System Apogee 1000Lite Digital Color Doppler Ultrasound Imaging System Apogee 1000Exp Digital Color Doppler Ultrasound Imaging System Apogee 1000B/W Digital Color Doppler Ultrasound Imaging System Apogee 1U Digital Color Doppler Ultrasound Imaging System Apogee 1T Digital Color Doppler Ultrasound Imaging System Apogee 1G Digital Color Doppler Ultrasound Imaging System
	Apogee 1000/ Apogee 1000Neo/ Apogee 1000Lite/ Apogee 1000Exp/ Apogee 1000B/W/ Apogee 1U/ Apogee 1T/ Apogee 1G
	Apogee 1000 series (Apogee 1000/ Apogee 1000Neo/ Apogee 1000Lite/ Apogee 1000Exp/ Apogee 1000B/W)/ Apogee 1 series (Apogee 1U/ Apogee 1T/ Apogee 1G) Digital Color Doppler Ultrasound Imaging System
	Apogee 1000 series/ Apogee 1 series