Aco Healthcare Co,. Ltd.
℅ Henry Huang
Manager of Product and Marketing
Rm. 520, Bldg. 53, No. 195, Sec. 4, Chungshin Rd., Chutung
Hsinchu, 31057
TAIWAN (R.O.C.)

June 25, 2021

Re: K211232
Trade/Device Name: Apache Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: April 19, 2021
Received: April 23, 2021

Dear Henry Huang:

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 and Part 809); 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)*

K211232

Device Name
Apache Ultrasound System

Indications for Use *(Describe)*

The Apache Ultrasound System is intended for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Abdominal, Fetal/Obstetric, Gynecological, Fetal Echo, Musculo-skeletal (conventional and superficial), Small Organ (including breast, scrotum, thyroid), Peripheral Vessel, Carotid, Urology, and Pediatric. The system provides diagnostic ultrasound imaging in B, Color Doppler, M, PW and Combined (B+M; B+CD) modes. The clinical environments where the system can be used include physician offices, clinics, hospitals, and clinical point-of-care for diagnosis of patients except environments where intensity of electromagnetic disturbances is high.
The Apache Ultrasound System is a portable ultrasound system intended for use in environments where healthcare is provided by trained healthcare professionals.

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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510(K) Summary

K211232

Submitter:	Aco Healthcare Co,. Ltd. Address: Rm. 520, Bldg. 53, No. 195, Sec. 4, Chunghsing Rd., Chutung, Hsinchu, 31057, Taiwan(R.O.C.) +886-3-5820446
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Email	Henry.huang@acohealthcare.com
Date Prepared:	April 19th, 2021
Device Name:	Apache Ultrasound System
Common Name:	Diagnostic Ultrasound System and Accessories
Regulation Number:	21 CFR 892.1550, 892.1560, 892.1570
Classification Name:	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasonic Transducer
Regulation Class	Class II
Product Code:	IYN
Subsequent Product Code:	IYO, ITX
Intended Use	Diagnostic ultrasound imaging and fluid flow analysis
Indications for Use:	The Apache Ultrasound System is intended for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Abdominal, Fetal/Obstetric, Gynecological, Fetal Echo, Musculo-skeletal (conventional and superficial), Small Organ (including breast, scrotum, thyroid), Peripheral Vessel, Carotid, Urology, and Pediatric. The system provides diagnostic ultrasound imaging in B, Color Doppler, M, PW and Combined (B+M; B+CD) modes. The clinical environments where the system can be used include physician offices, clinics,

hospitals, and clinical point-of-care for diagnosis of patients except environments where intensity of electromagnetic disturbances is high. The Apache Ultrasound System is a portable ultrasound system intended for use in environments where healthcare is provided by trained healthcare professionals.

Device Description

The Apache Ultrasound System is a portable color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications through wireless communication with an off-the-shelf (OTS) mobile device. This system is a general purpose, software controlled, diagnostic ultrasound system. Its basic function is to acquire ultrasound data and display the image in B-Mode, M-Mode, PW mode and Color Doppler or a combination of these modes.

The Apache Probe processes the ultrasound signal and transfers real-time scan image data to the Apache App through the wireless connection with the mobile device. The 64-channel beamforming architecture of the probe maximizes the utility of all imaging transducer elements to enhance the diagnostic utility and confidence provided by the system. The Apache App provides the interface for mode/setting control and image display, acquisition, and storage functions. The Apache App is compatible with Android and iOS based mobile devices. Verified devices include Samsung Galaxy Tab S6, Samsung Galaxy Tab S7, Samsung Galaxy S10, Samsung Galaxy S21, Google Pixel 4, HTC U11, LG G85 ThinQ, iPhone 11, iPhone 12, iPad Pro 11-inch (Gen2), and iPad Air (Gen4).

The clinical environments where the system can be used include physician offices, clinics, hospitals, and clinical point-of-care for diagnosis of patients except environments where intensity of electromagnetic disturbances is high.

The Apache Ultrasound System is a portable ultrasound system intended for use in environments where healthcare is provided by trained healthcare professionals.

Predicate Device

Equivalent devices are referred to as predicate devices in alignment with the FDA's standard terminology for comparable devices. The predicate device selected to demonstrate equivalence is the Clarius Ultrasound Scanner (K192107).

Determination of Substantial Equivalence

The subject device "Apache Ultrasound System" is a Track 3 system that adopt the same fundamental scientific technology as the predicate device "Clarius Scanner (K192107)". All indications for use introduced by the Apache Ultrasound System are same to at least one model of the predicate devices. Comparison between the predicate device and subject device is provided below:

Description	**Subject Device** Apache Ultrasound System	**Predicate Device** Clarius Ultrasound System **(K192107)**
Product Name	Apache Ultrasound System	Clarius Ultrasound Scanner
Prescription/OTC use	Prescription Use	Prescription Use
Regulation Number	21 CFR 892.1550	21 CFR 892.1550
Product Code	IYN, IYO, ITX	IYN, IYO, ITX
510(k) Track	Track 3	Track 3
Intended Use	Diagnostic ultrasound imaging and fluid flow analysis	diagnostic ultrasound imaging and fluid flow analysis
Indications for use		Ophthalmic
	Fetal	Fetal
	Abdominal	Abdominal

		Intraoperative (Abdominal organs & Vascular)
	Small Organ (Thyroid, Scrotum, Breast)	Small Organ (Thyroid, Prostate, Scrotum, Breast)
		Cephalic (adult)
		Trans-rectal
		Trans-vaginal
	Musculo-skeletal (conventional)	Musculo-skeletal (conventional)
	Musculo-skeletal (superficial)	Musculo-skeletal (superficial)
	Urology	Urology
	Gynecology	Gynecology
		Cardiac (adult)
		Cardiac(pediatric)
	Peripheral vessel	Peripheral vessel
		Needle guidance
	Pediatric	Pediatric
	Carotid	Carotid
Portability	Portable Ultrasound System	Portable Ultrasound System
Power Source	Li-Ion Battery	Li-Ion Battery
Wireless Communication	Wireless communication via IEEE 802.11g/n	Wireless communication via IEEE 802.11g/n Bluetooth
Display and Control	Android or iOS mobile device	Android or iOS mobile device

Mode of operation	- B-Mode - M-Mode - Color Doppler - - PW Doppler - Combined (B+M; B+CD)	- B-Mode - M-Mode - Color Doppler - Power Doppler - PW Doppler - Combined (B+M; B+CD; B+PD, B+PWD)

Non-Clinical Test

Non-clinical performance tests include measurement accuracy, system sensitivity, thermal, mechanical, electrical safety, patient-contact materials, cleaning and disinfection, software and acoustic output.

The non-clinical test results show the device is compliant with the following standards, and it is safe and effective for its intended use and performance.

Reference No.	Title of Standard
AAMI/ANSI ES60601-1	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, Mod). (General II (ES/EMC))
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Capability – Requirements and tests. (4th Edition)
IEC 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
IEC 60601-2-37	Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
IEC 62133	Secondary Cells and Batteries Containing Alkaline or Other Non-Acid Electrolytes - Safety Requirements for Portable Sealed Secondary Cells, And for Batteries Made from Them, For Use in Portable Applications [Including: Corrigendum 1 (2013)]
IEC 62366	Consolidated Version Medical Devices - Application of Usability Engineering to Medical Devices
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-5	Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
ISO 10993-10	Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization
IEC 62304	Medical Device Software - Software Life Cycle Processes
ISO 14971	Medical Devices - Applications of Risk Management to Medical Devices

Quality assurance measures applied to the system design and development include, but were not limited to risk analysis, product specifications, design reviews and verification and validation.

Clinical Testing

Apache Ultrasound System introduces no new indications for use, modes, features, or technologies relative to the predicate devices (Clarius Scanner) that require clinical testing. The clinical safety and effectiveness of ultrasound systems with these characteristics are well accepted for both predicate and subject devices.

Conclusion

Apache Ultrasound System is substantially equivalent to the predicate device. The Apache Ultrasound System function in a manner similar to and are intended for the same use as the predicate device. Based on the predicate device comparison of indications for use, labeling, acoustic output and general safety and effectiveness information, as well as the non-clinical performance test results, it is concluded that this device is as safe and effective as the predicate device for its intended use and performance, and is substantially equivalent to the predicate device.