Echolight S.p.A
Giuseppe Criscenti
Quality, Certification and Regulatory Manager
Via Raffaello Sanzio, 18
Lecce, LE 73100
ITALY

March 16, 2022

Re: K212851
Trade/Device Name: EchoSK and EchoSGyn Modules for EchoS Family devices
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, MUA
Dated: February 2, 2022
Received: February 8, 2022

Dear Giuseppe Criscenti:

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,

Jessica Lamb, Ph.D.
Assistant 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)*
K212851

Device Name
EchoSK and EchoSGyn modules for EchoS Family devices

Indications for Use *(Describe)*
1) EchoSK and EchoSGyn Modules are additional software/hardware modules for EchoS Family devices and they are additions in terms of indication for use of the legally marketed EchoS Family.

2) EchoSK optional module for EchoS Family devices is intended to provide images of, or signals from, inside the body acquired by an appropriately trained professional in a clinical setting for musculoskeletal applications. The EchoSK module can be used both with a convex or a linear probe.

3) EchoSGyn optional module for EchoS Family devices is intended to provide images of, or signals from, inside the body acquired by an appropriately-trained professional in a clinical setting for Fetal and OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures) applications. The EchoSGyn module can be used both with a convex or with an endocavitary probe.

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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K212851

Section 5 510(k) Summary

I. SUBMITTER

Applicant Information	Echolight S.p.A. Via Raffaello Sanzio, 18 73100 Lecce, Italy
Contact	Dr. Giuseppe Criscenti (Quality, Certification and Regulatory Manager)
Date Prepared	1st September 2021

II. DEVICE

Device Trade Name	EchoSK and EchoSGyn Modules for EchoSFamily devices
Common Name	Musculoskeletal and gynecologic modules for Ultrasound System
Classification Name: Regulation Number:	Ultrasonic pulsed echo imaging system 21 CFR 892.1560
Classification Name: Regulation Number:	Bone Sonometer 21 CFR 892.1180
Product Code	IYO, MUA

III. PREDICATE DEVICE

Legally Marketed Primary Predicate Device

510(k) Number	Pro Code	Trade Name	Applicant
K202683	21 CFR 892.1550	ACUSON Sequoia Diagnostic Ultrasound System, ACUSON SC2000 Diagnostic Ultrasound System, ACUSON Freestyle Diagnostic Ultrasound System, ACUSON S1000, S2000, S3000 Diagnostic Ultrasound Systems, ACUSON P200 Diagnostic Ultrasound System, ACUSON P500 Diagnostic Ultrasound System, ACUSON NX3, NX3 Elite Diagnostic Ultrasound System	Siemens Medical Solutions, USA, Inc.

Legally Marketed Additional Predicate Device

510(k) Number	Pro Code	Trade Name	Applicant
K202514	21 CFR 892.1180	EchoS Family	Echolight S.p.a.

IV. Device Description

EchoSK and EchoSGyn are optional modules for EchoS Family devices.

EchoSK is an optional module of the EchoStudio software that allows the operator to visualize echographic images for musculoskeletal applications. The EchoSK module can be used both with a convex or a linear probe.

EchoSGyn is an optional module of EchoStudio that allows the operator to visualize echographic images for gynecological/obstetric applications. EchoSGyn module can be used both with a convex or with an endocavitary probe.

V. Indication for Use

1) EchoSK and EchoSGyn Modules are additional software/hardware modules for EchoS Family devices and they are additions in terms of indication for use of the legally marketed EchoS Family.

2) EchoSK optional module for EchoS Family devices is intended to provide images of, or signals from, inside the body acquired by an appropriately trained professional in a clinical setting for musculoskeletal applications. The EchoSK module can be used both with a convex or a linear probe.

3) EchoSGyn optional module for EchoS Family devices is intended to provide images of, or signals from, inside the body acquired by an appropriately-trained professional in a clinical setting for Fetal and OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures) applications. The EchoSGyn module can be used both with a convex or with an endocavitary probe.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The subject device and the primary predicate device K202683 are both ultrasound devices intended to provide images of inside the body by an appropriately trained professional in a clinical setting for Fetal, OB/GYN and musculoskeletal applications.

EchoSK optional module is intended to provide images of, or signals from, inside the body by an appropriately trained professional in a clinical setting for musculoskeletal applications as the

analogous function performed by the primary predicate K202683 "ACUSON Sequoia Diagnostic Ultrasound System".

EchoSGyn optional module is intended to provide images of, or signals from, inside the body by an appropriately trained professional in a clinical setting for Fetal and OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures) applications as the analogous function performed by the primary predicate K202683 "ACUSON Sequoia Diagnostic Ultrasound System".

Considering the technological characteristics, the subject device and the primary predicate device K202683 are both portable and software controlled diagnostic ultrasound systems that transmit, receive and display ultrasound echo data.

Both subject device and ACUSON Sequoia Diagnostic Ultrasound System are powered by, and communicates with a computer. A transducer is used to generate and transmit ultrasound waves into the tissue. The reflected sound waves are detected and digitized before the data is transferred to the computer. Both devices, use an echographic probe that generates and transmits ultrasound waves into the tissue and the detected analog signals are converted into digital ones by means of an analog-to-digital converter.

Both the subject device and the ACUSON Sequoia Diagnostic Ultrasound System, respectively through "EchoSK" and ACUSON proprietary softwares, are used as similar device modules for musculoskeletal applications.

Both the subject device and the ACUSON Sequoia Diagnostic Ultrasound System, respectively through "EchoSGyn" and ACUSON proprietary softwares, are used as similar device modules for Fetal and OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures) applications.

In addition, the technological characteristics of the subject device are the same of the additional predicate EchoS Family K202514 because they share the same hardware (EchoS and EchoStation devices) and software (EchoStudio).

EchoSK and EchoSGyn can be considered as additional modules of EchoS Family devices meaning that the subject device includes also the bone sonometer (it is the same of the additional predicate device) and it is intended to be used as bone sonometer and for muscoloskeletal and gynecological ultrasound applications.

Considering the hardware, subject and additional predicate devices share identical hardware. In particular, the beamformer is equipped with three SMA connectors for the transmission of the analog radio frequency (RF) signal and the track synchronization signals (Line Trigger) and frame (Frame Trigger). The model used is the Echo Blaster 128 CEXT-1Z, size 62x215x165 (mm), weighing 1.6 kg and is powered by an external medical grade transformer that provides 12VDC, 4 A. This device is already CE certified, KFDA and FDA 510 (k).

The RF signal is suitably filtered and amplified, before being converted into a digital signal. The designed filter is a bandpass type: the lower cutoff frequency eliminates the noise introduced by the beamformer, the higher cutoff frequency eliminates any signal aliasing phenomena. The amplifier has a gain of 18dB.

The analog signal is converted into digital by means of an analog-to-digital converter (ADC) with a resolution of 16bit and a sampling frequency of 40MHz.

The data transmission block consists of an FPGA and a microcontroller: the first appropriately recomposes the data received from the converter and the second transfers them to the PC using the USB protocol.

The scanned frames are available in proprietary format on the PC.

The filtering, amplification, digitization and data transmission phases have been implemented on a single electronic board, with reduced dimensions. The connection between the beamformer and the designed electronic board takes place by means of coaxial cables with SMA connectors. The voltage from the external medical power supply is used to power both the beamformer and the electronic boards. Inside the ABS cover there is also a USB HUB with 4 ports, on 3 of which are connected: the USB Type A- Type B cable connected to the beamfomer, the USB type B - Mini USB cable connected to the data acquisition card, the encryption USB pendrive.

All the electronic components and the cables are enclosed in a plastic ABS case.

The ultrasound transducer is a convex probe (CE marked) and it has a nominal central operating frequency of 3.5MHz and a radius of curvature of 60 mm (field of view 59°).

The newly added transducers are:

The linear probes (CE marked) with a nominal central operating frequency of 7.5 MHz and a length of 4 cm (field of view of 39 mm) or 6 cm (field of view of 59 mm).

The endocavitary probe (CE marked) with a nominal central operating frequency of 6.5MHz and a radius of 10 mm (field of view 156°).

Considering the software, subject and additional predicate devices share identical software named EchoStudio. The subject device adds two additional software modules:

- EchoSK optional module for EchoS Family devices is intended to provide images of, or signals from, inside the body acquired by an appropriately trained professional in a clinical setting for musculoskeletal applications. The EchoSK module can be used both with a convex or a linear probe.
- EchoSGyn optional module for EchoS Family devices is intended to provide images of, or signals from, inside the body acquired by an appropriately-trained professional in a clinical setting for Fetal and OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures) applications. The EchoSGyn module can be used both with a convex or with an endocavitary probe.

VII. Performance Data

The part in contact with patient has been tested and it is compliant with:

Biocompatibility (according to ISO 10993)

The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous

Electrical Safety, Electromagnetic Compatibility EMC (according to EN 60601-1 and EN 60601-1-2)

The battery of testing included the following tests:

- Electrical Safety Test:(see attachment 15_A)
- Electromagnetic Compatibility: Test Report (see attachment 15_B and attachment 15_C)

Software Validation (According to ISO 62304)

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could not directly result in serious injury or death to the patient or operator.

The documentation of Software Validation can be found in the annexes of Section 14

Usability (According to IEC 62366-1:2015)

The usability of the product was conducted in accordance with IEC 62366-1:2015 and concerns various aspects of the device use.

The documentation can be found in the annexes of Section 16:

- Usability File (see Attachment 16_A)

ANIMAL STUDIES

None

PERFORMANCE TESTING - CLINICAL

None

VIII. Conclusions

Echolight S.p.A. has determined, by using comparisons and tests, that EchoSK and EchoSGYN modules for Echostudio software and EchoS Family devices are substantially equivalent to the listed predicate devices in terms of intended use, typical clinical use, operational characteristics, and fundamental technological characteristics. Any differences are considered minor and do not raise new issues of the safety and effectiveness of EchoSK and EchoSGYN modules for Echostudio software and EchoS Family devices device when compared to the predicate devices.