Sonivate Medical, Inc.
℅ Mr. Steve Hesler
Regulatory Affairs Contractor
4640 SW Macadam Avenue, Suite 200
PORTLAND OR 97239

February 25, 2020

Re: K192253
Trade/Device Name: SonicEye® Dual-Array Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: January 31, 2020
Received: February 5, 2020

Dear Mr. Hesler:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192253

Device Name

SonicEye® Dual-Array Ultrasound System

Indications for Use *(Describe)*

The SonicEye® Dual-Array Ultrasound System is for use in B-mode (grayscale) imaging of human subjects in the following clinical applications: Fetal, Cardiac (adult and pediatric), Abdominal, Pediatric, Peripheral vessel, Musculoskeletal (conventional and superficial), Small parts (breast, thyroid, testes), Thoracic/pleural.

The device is intended for use by medical professionals to include doctors, imaging technicians, emergency medicine and military corpsmen/medics that have been trained in basic sonography techniques. The use would include medical environments such as hospitals, clinics, military field aid stations.

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.

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510(k) Summary
(per 21 CFR 807.92)

Date prepared:
January 28, 2020

SUBMITTER:
Sonivate Medical Inc.
4640 SW Macadam Ave, Suite 200
Portland, OR 97239

Contact person:
Steve Hesler
503 260 8221
heslers@yahoo.com

DEVICE UNDER REVIEW

Proprietary name: SonicEye® Dual-Array Ultrasound System

Common name:
Diagnostic Ultrasound System

Classified name:
Ultrasonic Pulsed Echo Imaging
CFR 892.1560
Product code: IYO
Class II

Diagnostic Ultrasound Transducer
CFR 892.1570
Product code: ITX
Class II

PREDICATE DEVICE

The GE Vscan with Dual Probe ultrasound system has been cleared via K140693 dated May 16, 2014.

DEVICE DESCRIPTION

The SonicEye® Dual-Array Ultrasound System is a lightweight, battery-powered unit that contains an innovative dual-array fingertip transducer which incorporates two transducer arrays, a high-frequency linear and a low-frequency phased, in a single

easily-controlled fingertip design that can be worn on the fingertip or held between the thumb and forefinger like most ultrasound probes.

The transducer is hard-wired to an image processor module that is firmware controlled. The image processor controls the behavior of the device including; beamforming, image construction, and power management; and transmits acquired data via USB cable to a computer tablet, with proprietary SonicEye Application software installed. The Windows application allow the operator to view scanned images and to control the user-selectable features of the device.

The system operates in B-Mode ONLY.

INDICATIONS FOR USE

The SonicEye® Dual-Array Ultrasound System is for use in B-mode (grayscale) imaging of human subjects in the following clinical applications: Fetal, Cardiac (adult and pediatric), Abdominal, Pediatric, Peripheral vessel, Musculoskeletal (conventional and superficial), Small parts (breast, thyroid, testes), Thoracic/pleural.

The device is intended for use by medical professionals to include doctors, imaging technicians, emergency medicine and military corpsmen/medics that have been trained in basic sonography techniques. The use would include medical environments such as hospitals, clinics, military field aid stations.

COMPARISON TO PREDICATE DEVICE

Sonivate has identified a predicate device, the GE Vscan with Dual Probe Ultrasound System as a predicate product. The GE Vscan with Dual Probe ultrasound system has been cleared via K140693 dated May 16, 2014.

Both products employ the same technological features: the use of piezo-electric transducers to project focused beams of ultrasound energy into the human body then process the characteristics of the returned echo to create an image of soft tissues. Both products are software-controlled medical products that conform to accepted international standards for diagnostic ultrasound device performance,

Both products are portable and battery-operated

The differences between the two devices are: the GE Vscan is capable of operating in several modes (B mode, Color Doppler, Combined modes, and Harmonic Imaging). The SonicEye supports only B mode imaging.

PERFORMANCE DATA

The SonicEye system meets the following standards for medical devices:

Biocompatibility
- ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Electrical Safety-
- IEC 60601-1: Medical Electrical Equipment - PART 1: General Requirements for Basic Safety and Essential Performance
- 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

Electromagnetic Compatibility
- IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

Acoustic Output Testing
- NEMA UD 2: Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment

Risk Management
- ISO 14971: Medical devices - Application of risk management to medical devices

CLINICAL STUDIES

In a prospective, randomized, crossover trial the SonicEye Dual-Plane Ultrasound System was compared with the GE Vscan Extend (an FDA-cleared diagnostic ultrasound product device that also utilizes a single transducer with two arrays) for performance of an extended focused assessment using ultrasound in trauma (eFAST) on live humans and simulation models. The subjects were combat medics with no previous ultrasound experience; study volunteers included both men and women, ages 18-54 years. Subjects were all given a standardized 60-minute lecture on eFAST. The study concluded that the performance of the medics did not differ between the use of the SonicEye and the GE Vscan.

CONCLUSIONS

Based on the similarities in technology, the indications for use scanning human subjects, and the documented performance testing, the SonicEye Dual-Plane Ultrasound System is substantially equivalent to the predicate device and the benefits of use of the system on humans outweighs the risk.