April 22, 2022

iSono Health, Inc.
% Daniel Lehtonen
Regulatory Consultant
Compliance and Regulatory Services LLC
3771 Southbrook Dr.
DAYTON OH 45430

Re: K213620
Trade/Device Name: ATUSA™ Automated 3D Breast Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: March 18, 2022
Received: March 21, 2022

Dear Daniel Lehtonen:

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

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)*
K213620

Device Name

ATUSA™ Automated 3D Breast Ultrasound System

Indications for Use *(Describe)*

The device is indicated for use as a B-mode ultrasonic imaging system for imaging of a patient's breast when used with an automatic scanning linear array transducer. The device is not intended to be used as a replacement for screening mammography.

Operator: Trained Healthcare Professional

Patient Population: Ages 18 and above

Environment of use: Facilities where healthcare is provided - e.g. hospitals, clinics, physician offices, mobile care units.

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.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the Requirements of Safe Medical Device Systems Act 1990 and 21 CFR Sec. 807.92

510(k) Number: **K213620**

a1 APPLICANT INFORMATION:

Date Prepared:	22 April 2022
Name:	iSono Health, Inc.
Address:	395 Oyster Point Blvd. Suite 501 South San Francisco, CA 94080
Contact Person:	Shadi Saberi, PhD
Title:	Chief Technology Officer
Phone Number:	(415) 857-3073
Email:	shadi@isonohealth.com

a2 DEVICE:

Trade Name:	ATUSA™ Automated 3D Breast Ultrasound System
Common Name:	Ultrasound System
Classification Name:	System, Imaging, Pulsed Echo, Ultrasonic 21 CFR 892.1560 / 21 CFR 892.1570
Product Code:	IYO, ITX

a3 PREDICATE DEVICE:

Predicate Device:	K080555 [Cleared 03 Jun 2008]

The FDA database for recalls was searched on 24 Sep 2021 during the preparation of the 510(k) submission and no recalls for the device noted above were found.

a4 DESCRIPTION OF THE DEVICE:

The ATUSA™ Automated 3D Breast Ultrasound System is a battery operated Track 3 diagnostic ultrasound system intended for imaging of the breast. The device utilizes B-mode grayscale ultrasound via an automated linear transducer and consists of the following components:

1) Automated ultrasound scanner that integrates all hardware components including the transducer, electronics, and mechanical parts in a compact form factor. The scanner connects to a laptop via USB cable and automatically captures ultrasound images of the breast volume;
2) Positioning accessory that includes a pair of expandable cups, disposable straps, drain bags and mesh. The expandable cups are assembled as a wearable accessory with disposable straps to form the breast tissue conveniently in the field of view of the scanner and facilitate reproducible positioning of the scanner on the breast. The expandable cups come in different sizes to accommodate a range of breast sizes;
3) Charger base for wirelessly charging the scanner battery;
4) Software application to control the scanner operation, to acquire and display the images in real-time, and to perform advanced image processing, 3D reconstruction and visualization in various image planes.

a5 STATEMENT OF INTENDED USE:

The device is indicated for use as a B-mode ultrasonic imaging system for imaging of a patient's breast when used with an automatic scanning linear array transducer. The device is not intended to be used as a replacement for screening mammography.

Operator: Trained Healthcare Professional

Patient population: Ages 18 and above

Environment of use: Facilities where healthcare is provided - e.g. hospitals, clinics, physician offices, mobile care units.

a6 TECHNOLOGICAL CHARACTERISTIC COMPARISON:

Both the subject and predicate devices are diagnostic ultrasound devices. Ultrasound imaging is based on the use of a device which converts electrical energy to sound, emits the sound waves into the target tissue and 'listens' for the return echo which is converted back to electrical pulses and processed into an image. In both devices the transducer is controlled by a computer via proprietary software.

The subject and predicate devices are based on the following same technological principles:

- B mode diagnostic ultrasound imaging via the use of an automated linear transducer to acquire serial 2D grayscale images of the entire breast
- Software controlled ultrasound image capture and processing
- Use previously cleared linear array transducers
- Breast tissue is immersed in fluid environment

The following technological differences exist between the subject and predicate devices:

- The subject device scanner powered by a rechargeable battery whereas the predicate device is line powered. The change in energy source does not impact the safety or effectiveness of the device. Compliance with applicable electrical safety standards support equivalence.
- The subject device transducer operates between 5 and 10 MHz, the predicate device transducer operates at 5 - 13 MHz. The difference in the upper frequency range does not impact the safety or efficacy of the device.
- The patient is in a supine position for the subject device versus a prone position for the predicate device. A supine positioned patient is common and the difference in patient positioning does not impact the safety or efficacy of the device.

b1/2 SAFETY AND PERFORMANCE TESTING AND VALIDATION:

The following system design verification testing was successfully completed:

- Electrical Safety
- Electromagnetic compatibility (EMC)
- Acoustic Output Testing
- Performance Testing

Referenced Standards:

- IEC 60601-1:2005 +A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.0 2014-02 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 Edition 2.1 2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 62359 Edition 2.1 2017-09 CSV Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields
- ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Performance Testing

- ATUSA™ System Requirement Verification Detailed Test Report
- ATUSA™ Scanner Imaging Performance Test Report

Software Verification and Validation Testing

Software verification and validation testing were conducted following the FDA guidance document for software contained in medical devices. The software was considered to be a "moderate" level of concern since a failure or latent flaw could indirectly result in a minor injury to the patient through incorrect or delayed information or through action of the operator.

Device Validation Testing

The ATUSA™ System has undergone validation testing including feasibility, usability, and human factors evaluation to validate the ATUSA System and accessories met their respective user requirements. The initial feasibility assessment was performed to validate the design of the ATUSA™ System with respect to the device function and the positioning accessory fit and comfort for the patient. Validation of the usability and human factors considerations consisted of simulated users and simulated patients using the ATUSA™ System and accessories. The testing was conducted in a simulated exam room replicating a typical professional use environment. Sample clinical images were reviewed by board-certified radiologists who validated that the gray scale B-mode images have adequate image quality for visualizing breast tissue structures.

b3 CONCLUSIONS DRAWN FROM TESTING:

The safety, performance and validation testing data demonstrate that the ATUSA™ Automated 3D Breast Ultrasound System meets the device requirements supporting its intended use and is substantially equivalent in technological characteristics, principles of operation and indications for use to the predicate device. Any noted differences do not raise any new issues of safety and effectiveness. Therefore, the ATUSA system is as safe and as effective as the predicate device.