EchoNous, Inc.
℅ Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

July 10th, 2018

Re: K181574
Trade/Device Name: Uscan
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: June 14, 2018
Received: June 15, 2018

Dear Mr. Job:

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. 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.

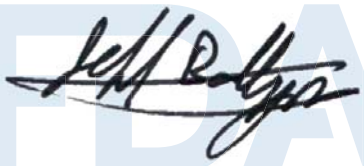
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*

K181574

Device Name
Uscan

Indications for Use *(Describe)*
The Uscan is for non-invasive imaging of the human body and is intended for the following applications: Abdominal, Musculoskeletal, Pediatric, Small Organ, and Peripheral Vessel. Users must have ultrasound training for abdominal, musculoskeletal, pediatric, small organ, and peripheral vessel imaging.

The Uscan can also be used to obtain an image of the bladder that is used to automatically determine bladder volume.

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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"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."

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Uscan

TABLE 1.3-1: USCAN INDICATIONS FOR USE FORM

System: Uscan
Intended Use: Diagnostic ultrasound imaging of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P						
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P						
	Small Organ (Specify)	P						1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P						
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N						2
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
1: Small organ imaging is prostate.
2: Includes imaging to assist in the placement of needles and catheters in vascular structures.

All items marked "P" were previously cleared in 510(k) K160420.

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.

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Uscan

TABLE 1.3-2: USCAN INDICATIONS FOR USE FORM

System: Uscan
Transducer: Uscan Sector Probe (B3-5)
Intended Use: Diagnostic ultrasound imaging of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P						
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P						
	Small Organ (Specify)	P						1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P						
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
Additional Comments:
1: Small organ imaging is prostate.
2: Includes imaging to assist in the placement of needles and catheters in vascular structures.

All items marked "P" were previously cleared in 510(k) K160420.

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.

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Uscan

TABLE 1.3-3: USCAN INDICATIONS FOR USE FORM

System: Uscan
Transducer: Uscan Linear Probe (L14-6)
Intended Use: Diagnostic ultrasound imaging of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N						2
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
Additional Comments:
1: Small organ imaging is prostate.
2: Includes imaging to assist in the placement of needles and catheters in vascular structures.

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.

510(k) Summary

1. Submitter:

EchoNous, Inc.
8310 154th Ave NE
Bldg B, Ste 200
Redmond, WA 98052
USA

2. Contact Person:

Trish Liau
Regulatory Affairs Manager
Telephone: (425) 402-4044
E-mail: patricia.liau@echonous.com

3. Date Prepared:

March 30, 2018

4. Proprietary/Marketed Names:

Uscan *(subject to change)*

5. Common/Usual Name:

Diagnostic ultrasound system with accessories

6. Classification:

Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology

Name	21 CFR Number	Product Code
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

7. Predicate Devices:

Primary predicate: Uscan Ultrasound System (K160420)
Reference predicate: SonoSite SII Ultrasound System (K162045)

8. Device Description:

The Uscan is a hand-held, diagnostic ultrasound system with an on-screen display. Its purpose is to acquire ultrasound echo data and display it in B-Mode on an off-the-shelf display. Automated bladder volume measurements are supported.

9. Intended Use:

The Uscan is for non-invasive imaging of the human body and is intended for the following applications: Abdominal, Musculoskeletal, Pediatric, Small Organ, and Peripheral Vessel. Users must have ultrasound training for abdominal, musculoskeletal, pediatric, small organ, and peripheral vessel imaging.

The Uscan can also be used to obtain an image of the bladder that is used to automatically determine bladder volume.

10. Technological Characteristics:

The Uscan and SII ultrasound systems are Track 3 devices that employ the same fundamental scientific technology. A comparison table is provided below.

Feature	Uscan Ultrasound System (This submission)	Uscan Ultrasound System (K160420)	SonoSite SII Ultrasound System (K162045)
Intended Use	Diagnostic ultrasound imaging of the human body	Diagnostic ultrasound imaging of the human body	Diagnostic ultrasound imaging or fluid flow analysis of the human body
Indications for Use	Abdominal Pediatric Small Organ (prostate) Musculo-skeletal (Conventional) Peripheral Vessel Needle guidance	Abdominal Pediatric Small Organ (prostate) Musculo-skeletal (Conventional)	Opthalmic Fetal – OB/GYN Abdominal Pediatric Small Organ (breast, thyroid, testicle, prostate) Neonatal Cephalic Adult Cephalic Trans-Rectal Trans-Vaginal Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Cardiac Adult Cardiac Pediatric Peripheral Vessel Needle guidance
Transducer Types	Linear Array Annular Array	 Annular Array	Linear Array Curved Linear Array Intracavitary Phased Array
Transducer Frequency	3.0 – 14.0 MHz	3.0 – 7.0 MHz	1.0 – 15.0 MHz
Modes of Operation	2D / B-mode	2D / B-mode	2D / B-mode Tissue Harmonic Imaging M-mode Color M-mode Color Power Doppler Combination Modes Velocity Color Doppler
PW Doppler	Not available	Not available	Not available
CW Doppler	Not available	Not available	Not available

Feature	Uscan Ultrasound System (This submission)	Uscan Ultrasound System (K160420)	SonoSite SII Ultrasound System (K162045)
Patient Contact Materials	**Transducers:** ABS+PC (acrylonitrile butadiene styrene + polycarbonate) Cycoloy Polymethyl Pentene based Olefin Copolymer Silicone Rubber RTV Thermoplastic polyurethane	**Transducers:** Cycoloy Polymethyl Pentene based Olefin Copolymer Thermoplastic polyurethane	**Transducers:** Acrylonitrile-butadiene-styrene (ABS) Cycoloy Polycarbonate (PC) Polysulfone Poly-Vinyl-Chloride (PVC) Silicone Rubber Silicone Rubber RTV Urethane **Needle Guides:** Acetal copolymer Acrylonitrile-butadien-styrene (ABS)
System Characteristics	**Uscan:** Handheld tablet (off-the-shelf) 9.7" Liquid Crystal Display (LCD) Operating system: Android Uscan ultrasound software running as an "app" on tablet 1 Micro USB port Dimensions: 9.34"(H) x 6.65"(W) x 0.24"(L) Weight: 0.39 lbs System operates via battery Input: 100 – 240 VAC, 50/60 Hz Output: 5VDC, 2 A max Distance calculations Wireless networking	**Uscan:** Handheld tablet (off-the-shelf) 7.86" Liquid Crystal Display (LCD) Operating system: Android Uscan ultrasound software running as an "app" on tablet 1 Micro USB port Dimensions: 8.15"(H) x 5.39"(W) x 0.31"(L) Weight: 0.77 lbs System operates via battery Input: 100 – 240 VAC, 50/60 Hz Output: 12VDC, 1.5 A max Distance, volume calculations Wireless networking	**SII:** Handheld display and control 12.1" Liquid Crystal Display (LCD) Operating system: Windows CE 3 USB ports Dimensions: 4.8"(H) x 11.5"(W) x 17.6"(L) Weight: 12.6 lbs System operates via battery or AC power Input: 100 – 240V options, 50/60 Hz Output: 15VDC Various obstetrical, cardiac, volume, and M-mode measurement and calculation packages Wireless networking
510(k) Track	Track 3	Track 3	Track 3

11. Basis for Substantial Equivalence:

Summary of Non-Clinical Tests

The Uscan has been designed and evaluated to comply with the following FDA recognized standards.

Reference No.	Title
ISO 10993-1	AAMI / ANSI / ISO 10993-1:2009/(R)2013, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
IEC 60601-1	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)
IEC 60601-1-2	AAMI / ANSI / IEC 60601-1-2:2014, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-6	IEC 60601-1-6 Edition 3.1 2013-10, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-2-37	IEC 60601-2-37:2015 Edition 2.1, Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 62304	AAMI / ANSI / IEC 62304:2006, Medical device software - Software life cycle processes
IEC 62366	AAMI / ANSI / IEC 62366-1:2015, Medical devices – Part 1: Application of usability engineering to medical devices
ISO 14971	ISO 14971:2007, Medical devices - Application of risk management to medical devices
NEMA UD 2-2004	NEMA UD 2-2004 (R2009), Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment

The Uscan has been bench tested for imaging performance and measurement accuracy, with tests showing the Uscan imaging performance and measurement accuracy to be substantially equivalent to the predicate devices.

Verification and validation reports, traceability, and risk analysis demonstrate the Uscan operates as intended and risks mitigated have been verified.

The conclusion from the testing is the device is safe and effective for its intended use, and performs as well or better than the predicate devices.

The Uscan system and predicates meet FDA requirements for Track 3 devices, share indications for use, have biosafety equivalence, and conform to applicable electromedical device safety standards. EchoNous, Inc. believes the Uscan is substantially equivalent with regard to safety and effectiveness to the predicate devices.