EchoNous, Inc.
℅ Ms. Trish Liau
Regulatory Affairs Manager
8310 154th Avenue NE, Bldg B., Suite 200
REDMOND WA 98052

March 26, 2020

Re: K193518
Trade/Device Name: KOSMOS
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, DQD, DPS
Dated: February 29, 2020
Received: March 3, 2020

Dear Ms. Liau:

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)*
K193518

Device Name
KOSMOS

Indications for Use *(Describe)*

KOSMOS is intended to be used by qualified and trained healthcare professionals in the clinical assessment of the cardiac and pulmonary systems and the abdomen by acquiring, processing, displaying, measuring, and storing synchronized ultrasound images, electrocardiogram (ECG) rhythms, and digital auscultation (DA) sounds and waveforms.

With respect to its ultrasound imaging capabilities, KOSMOS is a general purpose diagnostic ultrasound system used in the following clinical applications and modes of operation:

- Clinical Applications: Cardiac, Thoracic/Lung, Abdominal, Peripheral Vascular, and Image Guidance for Needle/Catheter Placement
- Modes of Operation: B-mode, M-mode, Color Doppler, Combined Modes of B+M and B+CD, and Harmonic Imaging

KOSMOS is intended to be used in clinical care and medical education settings on adult and pediatric patient populations.

The device is non-invasive, reusable, and intended to be used on one patient at a time.

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 K193518

1. Submitter

EchoNous, Inc.
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USA

2. Contact Person

Trish Liau
Regulatory Affairs Manager
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3. Date Prepared

December 17, 2019

4. Device / Marketing Trade Name

KOSMOS *(subject to change)*

5. Common / Usual Name

Diagnostic ultrasound system with integrated electronic stethoscope and electrocardiograph

6. Classification

Regulatory Device Class: II
Classification Panel: Radiology, Cardiovascular

Classification Name	21 CFR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX
Electronic Stethoscope	870.1875	DQD
Electrocardiograph	870.2340	DPS

7. Predicate Devices

Primary predicate device: GE Vscan Extend (K180995); Product Code: IYN, IYO, ITX
Secondary predicate device: Eko Duo Model E5 (K170874); Product Code: DQD, DPS

8. Device Description

KOSMOS consists of a tablet and probe, which connects to the tablet via a cable. Its accessories include a power charger, ECG cable, and binaural headset. KOSMOS can operate on battery or while connected to mains.

The probe face houses an ultrasound transducer and sealed microphones for auscultation. The tablet can display clinical and patient data information including the display of ultrasound images, auscultation and ECG waveforms, and patient data/reports. The

tablet also includes speakers for sounds associated with system control and feedback. Additionally, the tablet offers a means of user control with its touchscreen display and buttons.

Although its intended operation is not dependent on Wi-Fi, KOSMOS supports Wi-Fi connectivity for patient data archival.

The tablet can be positioned on a flat surface close to the patient while the user holds the probe with one hand to scan the patient. The user's other hand is then free to interact with the tablet using its touchscreen and buttons. The user can also hold the tablet in one hand and the probe in the other hand to scan the patient.

KOSMOS' ECG capability provides a timing reference with respect to the cardiac cycle as compared with both ultrasound imaging and digital auscultation. Ultrasound imaging, ECG, and DA are all integrated into the probe in a time-synchronized manner.

KOSMOS' 3-lead single-channel ECG allows for the acquisition and display of a single ECG waveform (lead), which can be any one of the Lead I, Lead II, or Lead III waveforms. One end of the ECG cable connects to the probe via a custom-designed magnetic connector. The other end has three (3) RA/LA/LL leadwires to be connected to user-supplied clip-style electrodes affixed to the patient using the standard RA/LA/LL configuration.

9. Intended Use / Indications for Use

KOSMOS is intended to be used by qualified and trained healthcare professionals in the clinical assessment of the cardiac and pulmonary systems and the abdomen by acquiring, processing, displaying, measuring, and storing synchronized ultrasound images, electrocardiogram (ECG) rhythms, and digital auscultation (DA) sounds and waveforms.

With respect to its ultrasound imaging capabilities, KOSMOS is a general purpose diagnostic ultrasound system used in the following clinical applications and modes of operation:

- Clinical Applications: Cardiac, Thoracic/Lung, Abdominal, Peripheral Vascular, and Image Guidance for Needle/Catheter Placement
- Modes of Operation: B-mode, M-mode, Color Doppler, Combined Modes of B+M and B+CD, and Harmonic Imaging

KOSMOS is intended to be used in clinical care and medical education settings on adult and pediatric patient populations.

The device is non-invasive, reusable, and intended to be used on one patient at a time.

Type of Use: Prescription Use (Part 21 CFR 801 Subpart D)

10. Basis for Substantial Equivalence

KOSMOS is substantially equivalent to its predicate devices with regards to intended use, technological characteristics, and safety and effectiveness. A comparison table is provided below.

Feature	KOSMOS System (This 510(k) submission)	GE Vscan Extend Ultrasound System (K180995)	Eko Duo Model E5 (K170874)
Intended Use / Indications for Use	KOSMOS is intended to be used by qualified and trained healthcare professionals in the clinical assessment of the cardiac and pulmonary systems and the abdomen by acquiring, processing, displaying, measuring, and storing synchronized ultrasound images, electrocardiogram (ECG) rhythms, and digital auscultation (DA) sounds and waveforms. With respect to its ultrasound imaging capabilities, KOSMOS is a general purpose diagnostic ultrasound system used in the following clinical applications and modes of operation: • Clinical Applications: Cardiac, Thoracic/Lung, Abdominal, Peripheral Vascular, and Image Guidance for Needle/Catheter Placement • Modes of Operation: B-mode, M-mode, Color Doppler, Combined Modes of B+M and B+CD, and Harmonic Imaging KOSMOS is intended to be used in clinical care and medical education settings on adult and pediatric patient populations. The device is non-invasive, reusable, and intended to be used on one patient at a time. Type of Use: Prescription Use (Part 21 CFR 801 Subpart D)	Vscan Extend is a general purpose diagnostic ultrasound imaging system for use by qualified and trained healthcare professionals enabling visualization and measurement of anatomical structures and fluid. Its pocket-sized portability and simplified user interface enables integration into examination and training sessions indoors and in other environments described in the user manual. The information can be used for basic/focused assessments and adjunctively with other medical data for clinical diagnosis purposes during routine, periodic monitoring, and triage. With the phased array transducer on the sector probe, the specific clinical applications and exam types include: Cardiac; Abdominal; Renal; OB/GYN; Urology; Fetal, Evaluation of Presence of Fluid; Imaging Guidance for Needle/Catheter Placement (e.g. paracentesis, pericardiocentesis, thoracentesis, amniocentesis); Peripheral Vascular Imaging (e.g. arteries and veins); Thoracic/Lung (e.g. pleural motion/sliding, line artifacts); Adult Cephalic; and Pediatrics. With the addition of the linear array transducer on the single dual headed probe solution, the specific clinical applications and exam types are expanded to include: Peripheral vascular imaging (e.g. lower extremity, carotid); Procedure Guidance for Arterial or Venous Vessels (e.g. central lines, upper extremity); Small Organs (e.g. thyroid); Musculoskeletal (Long Bone; Hip, shoulder, elbow and Knee Joints); Evaluation of Presence of Fluid; Thoracic/Lung (e.g. pleural motion/sliding, line artifacts); and Pediatrics. Type of Use: Prescription Use (Part 21 CFR 801 Subpart D)	The Eko Model E5 System is intended to be used by healthcare professionals to electronically amplify, filter, and transfer body sounds and single-channel electrocardiogram (ECG) waveforms. The Eko Model E5 System also displays ECG waveforms and phonocardiogram waveforms on the accompanying mobile application for storage and sharing (when prescribed or used under the care of a physician). It can be used to record heart sounds and cardiac murmurs, bruits, respiratory sounds, and abdominal sounds during physical examination in normal patients or those with suspected diseases of the cardiac, vascular, pulmonary, or abdominal organ systems. The device can be used on adults and pediatrics. The data offered by the device is only significant when used in conjunction with physician over read as well as consideration of other relevant patient data. The device should not be used on infants weighing less than 10kg. Type of Use: Prescription Use (Part 21 CFR 801 Subpart D)

Feature	KOSMOS System (This 510(k) submission)	GE Vscan Extend Ultrasound System (K180995)	Eko Duo Model E5 (K170874)
Ultrasound Substantial Equivalence (Technological Characteristics)			
Transducer Types	Phased Array	Phased Array Linear Array	
Clinical Applications	**Phased Transducer:** *Anatomy/ Region of Interest*: Abdominal Pediatric Cardiac Adult Cardiac Pediatric Peripheral Vascular Thoracic/Lung *Interventional Guidance*: Nonvascular	**Phased Transducer (only):** *Anatomy/ Region of Interest*: Fetal – OB/GYN Abdominal Pediatric Adult Cephalic Cardiac Adult Cardiac Pediatric Peripheral Vascular Thoracic/Pleural *Interventional Guidance*: Nonvascular	
Transducer Frequency	1.5 – 4.5 MHz	1.7 – 3.8 MHz	
Modes of Operation	2D / B-mode M-mode Color Doppler Combination Modes Harmonic Imaging	2D / B-mode Color Doppler Combination Modes Harmonic Imaging	
PW Doppler	Not available	Not available	
CW Doppler	Not available	Not available	
510(k) Track	Track 3	Track 3	
DA and ECG Substantial Equivalence (Technological Characteristics)			
DA Pickup Sensor and Processing	Audio microphone + digital signal processing Sampling Rate: 12.7 kHz		Audio microphone + digital signal processing Sampling Rate: 4000 Hz
DA Filter Modes	Heart/Midrange (50 – 600 Hz)		Diaphragm (100 – 500 Hz), Bell (20 – 200 Hz, Midrange (50 – 500 Hz), Extended ((20 – 2000 Hz)
DA Sound Amplification	Analog gain: 20 dB; Digital gain: user adjustable up to 25 dB		Amplifies up to 60x
DA Volume Control	Yes; 15 volume steps available		Yes; 12 volume settings
DA Ambient Noise Reduction	Yes		Yes
DA Direct Listening	Sounds can be listened to in real time using a digital-to-analog binaural headset		Digital-only sound mode
ECG Non-Continuous Monitoring Leads	3-lead, single-channel, user-supplied commercial electrodes		Single-channel, 2 stainless steel electrodes
ECG Anatomical Sites	Chest (torso) and Leg		Chest
ECG Leadwires and Trunk Assembly	Combines trunk cable and three leadwires into a single, non-sterile, reusable assembly that forms a conduction channel for transmitting signals from user-supplied clip-style electrodes affixed to patient skin to the Kosmos Torso (probe)		No
DA and ECG Visualization	Sounds and ECG waveforms can be visualized and recorded on the Kosmos Bridge (tablet) with or without an internet connection		Sounds and ECG tracings can be visualized on a Bluetooth device using the Eko App. The app can be used to visualize waveforms and tracings without an internet connection; however an internet connection is necessary to save the data.

Feature	KOSMOS System (This 510(k) submission)	GE Vscan Extend Ultrasound System (K180995)	Eko Duo Model E5 (K170874)
System Characteristics			
Dimensions and Weight	Handheld tablet display unit (proprietary): 146 x 216 x 59 mm, 657 g Display: 8” Probe: 150 x 56 x 35 mm, 260 g	Handheld tablet display unit (proprietary): 168 x 76 x 22 mm, 321 g Display: 12.7 cm, 720 x 1280 pixels resolution Sector probe: 129 x 32 x 25 mm, 85 g Dual probe: 129 x 39 x 38 mm, 120 g	Handheld Unit: 119 x 47 x 16 mm Weight: 208 g
Power Source	Mains and battery operated (rechargeable lithium ion battery)	Battery operated	Battery operated (rechargeable lithium ion battery)
Patient Contact Materials	Probe Lens: RTV silicone 664 Probe Housing: Polysulfone thermoplastic Probe Cemented Joint: RTV silicone 832 ECG Leadwires: Thermoplastic urethane	Unknown (information not publicly available); however, transducer material and other patient contact materials are biocompatible	6061 machined aluminum enclosure High-impact ABS thermoplastic
Ingress Protection (IP) Rating	Tablet: IP22 Probe: IPX7	Unit: IP33 Probe: IPX7	IP55
DICOM	Yes	Yes	No
Wireless Networking	Wireless networking (IEEE 802.11 b/g/n/ac supported)	Wireless networking (IEEE 802.11 b/g/n supported)	Wireless networking (Bluetooth 4.0 low-energy)

11. Non-Clinical Performance Data

KOSMOS has been designed and evaluated to comply with the following applicable FDA-recognized consensus standards. All verification and validation testing for KOSMOS confirms that product specifications are met and are equivalent in design and technological and performance characteristics as the predicate devices.

- ANSI AAMI ES60601-1:2005/(R)2012 ANSI AAMI 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)
- ANSI AAMI IEC 60601-2-27:2011(R)2016 Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment *(limited set of test requirements)*
- ANSI AAMI EC53:2013 ECG Trunk Cables And Patient Leadwires *(limited set of test requirements)*
- ANSI AAMI IEC 60601-1-2:2014 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests
- 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
- ANSI AAMI IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
- 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
- NEMA UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3
- IEC 62359 Edition 2.1 2017-09 CONSOLIDATED VERSION Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related

to medical diagnostic ultrasonic fields

- ANSI AAMI IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes [Including Amendment 1 (2016)]
- ANSI AAMI ISO 10993-1:2009/(R)2013 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ANSI AAMI ISO 14971:2007/(R)2010 (Corrected 4 October 2007) Medical devices - Applications of risk management to medical devices

12. Clinical Performance Data

An assessment of clinical performance data for KOSMOS was not required to support a determination of substantial equivalence.

13. Conclusion

EchoNous, Inc. considers KOSMOS to be substantially equivalent to its predicate devices with regards to intended use, technological and performance characteristics, and safety and effectiveness.