EchoNous, Inc.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

August 6, 2021

Re: K212100
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: July 3, 2021
Received: July 6, 2021

Dear Prithul Bom:

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 and Part 809); 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212100

Device Name
Kosmos

Indications for Use *(Describe)*
Kosmos is intended to be used by qualified and trained healthcare professionals in the clinical assessment for the following clinical applications by acquiring, processing, displaying, measuring, and storing ultrasound images, or 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, Vascular/Peripheral Vascular, Musculoskeletal, and interventional guidance (includes needle/catheter placement, fluid drainage, and nerve block)
• Modes of Operation: B-mode, M-mode, Color Doppler, Pulsed-Wave (PW) Doppler, Continuous-Wave (CW) Doppler, Combined Modes of B+M, and B+CD, B+PW, B+CW, 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

As required by 21, CFR Section 807.92

1. Submitter

EchoNous, Inc.
8310 154th Ave NE
Building B, Suite 200
Redmond, WA 98052
USA

2. Contact Person

Carly Hom
Manager, RA/QA
Telephone: (602)315-5728
E-mail: carly.hom@echonous.com

3. Date Prepared

August 4, 2021

4. Device / Marketing Trade Name

Kosmos

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

Predicate device: Kosmos (K193518); Product Code: IYN, IYO, ITX, DQD, DPS

Reference device: Vscan Air (K202035); Product Code: IYN, IYO, ITX

8. Device Description

Kosmos consists of a tablet (i.e., Kosmos Bridge or supported Off-The-Shelf Android tablet provided by the user) and probe (i.e., Kosmos Torso, Torso-One, or Lexsa), which connects to the tablet via a cable. Additional components include the ECG Patient Cable and Binaural Headset for use with Kosmos Torso only. Kosmos can operate on battery or while connected to mains, when used as either handheld device or mounted to the mobile stand (i.e., AI Station 2).

The probe face houses an ultrasound transducer and sealed microphones for auscultation (Kosmos Torso only).

The tablet (i.e., Kosmos Bridge or supported Off-The-Shelf Android tablet provided by the customer) displays clinical and patient data information including the display of ultrasound images, auscultation and ECG waveforms (when connected to Kosmos Torso), 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,
- updating the embedded Kosmos Software (Kosmos Bridge configurations only), or
- downloading or updating the Kosmos Software Application from the Google Play Store (Kosmos On Android configuration only)

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 Kosmos Torso 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 Kosmos' 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.

Kosmos is an FDA-cleared medical device; however, the new AI-assisted EF Workflow and Trio tool are not yet cleared by the FDA. Instead, EchoNous is following the Enforcement Policy for Imaging Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, Guidance for Industry and Food and Drug Administration Staff, April 2020 for this new feature.

9. Intended Use / Indications for Use

Kosmos is intended to be used by qualified and trained healthcare professionals in the clinical assessment for the following clinical applications by acquiring, processing, displaying, measuring, and storing ultrasound images, or 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, Vascular/Peripheral Vascular, Musculoskeletal, and interventional guidance (includes needle/catheter placement, fluid drainage, and nerve block)
- Modes of Operation: B-mode, M-mode, Color Doppler, Pulsed-Wave (PW) Doppler, Continuous-Wave (CW) Doppler, Combined Modes of B+M, and B+CD, B+PW, B+CW, 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 device with regards to intended use, technological characteristics, and safety and effectiveness. A comparison between the subject device, predicate device, and reference device are provided in the table below.

Feature	Subject Device: Kosmos (This 510(k) Submission)	Predicate Device: Kosmos (K193518)	Reference Device: Vscan Air (K202035)	Comparison
Intended Use / Indications for Use	Kosmos is intended to be used by qualified and trained healthcare professionals in the clinical assessment for the following clinical applications by acquiring, processing, displaying, measuring, and storing ultrasound images, or 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, Vascular/Peripheral Vascular, Musculoskeletal, and interventional guidance (includes needle/catheter placement, fluid drainage, and nerve block) • Modes of Operation: B-mode, M-mode, Color Doppler, Pulsed-Wave (PW) Doppler, Continuous-Wave (CW) Doppler, Combined Modes of B+M, and B+CD, B+PW, B+CW, and Harmonic Imaging Kosmos is intended to be used in clinical care and medical education settings on adult and pediatric patient populations.	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 Air is a battery-operated software-based general-purpose ultrasound imaging system for use by qualified and trained healthcare professionals or practitioners that are legally authorized or licensed by law in the country, state or other local municipality in which he or she practices. The users may or may not be working under supervision or authority of a physician. Users may also include medical students working under the supervision or authority of a physician during their education / training. The device is enabling visualization and measurement of anatomical structures and fluid including blood flow. Vscan Air's pocket-sized portability and simplified user interface enables integration into training sessions and examinations in professional healthcare facilities (ex. Hospital, clinic, medical office), home environment, road/air ambulance and other environments as 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 follow-up, and triage. Vscan Air supports Black/ white (B-mode), Color flow (Color doppler), Combined (B + Color Doppler) and Harmonic imaging modes with both the curved and linear	Addition of the following Clinical Applications: • Vascular • Musculoskeletal • Fluid Drainage • Nerve Block Addition of the following modes of operation: • Pulsed-Wave (PW) Doppler • Continuous-Wave (CW) Doppler • Combined Modes of B+PW and B+CW

Feature	Subject Device: Kosmos (This 510(k) Submission)	Predicate Device: Kosmos (K193518)	Reference Device: Vscan Air (K202035)	Comparison
	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)		array transducers. With the curved array transducer of the dual headed probe solution, the specific clinical applications and exam types include: abdominal, fetal/obstetrics, gynecological, urology, thoracic/lung, cardiac (adult and pediatric, 40 kg and above), vascular/peripheral vascular, musculoskeletal (conventional), pediatrics, interventional guidance (includes free hand needle/catheter placement, fluid drainage, nerve block and biopsy). With the linear array transducer of the dual headed probe solution, the specific clinical applications and exam types include: vascular/peripheral vascular, musculoskeletal (conventional and superficial), small organs, thoracic/lung, ophthalmic, pediatrics, neonatal cephalic, interventional guidance (includes free hand needle/catheter placement, fluid drainage, nerve block, vascular access and biopsy). Type of Use: Prescription Use (Part 21 CFR 801 Subpart D)	
Ultrasound Substantial Equivalence (Technological Characteristics)				
Transducer Types	• Phased Array • Linear Array	• Phased Array	• Curved Array • Linear Array	Addition of Linear Array Transducer

Feature	Subject Device: Kosmos (This 510(k) Submission)	Predicate Device: Kosmos (K193518)	Reference Device: Vscan Air (K202035)	Comparison
Clinical Applications	**Phased Array Transducer:** *Anatomy/ Region of Interest*: • Abdominal • Pediatric • Cardiac Adult • Cardiac Pediatric • Peripheral Vascular • Thoracic/Lung *Interventional Guidance*: • Nonvascular	**Phased Array Transducer:** *Anatomy/ Region of Interest*: • Abdominal • Pediatric • Cardiac Adult • Cardiac Pediatric • Peripheral Vascular • Thoracic/Lung *Interventional Guidance*: Nonvascular		Remains unchanged
	Linear Array Transducer: *Anatomy/ Region of Interest*: • Vascular/Peripheral Vascular • Musculoskeletal *Interventional guidance* • Needle/catheter placement • Fluid drainage • Nerve block		**Linear Array Transducer:** *Anatomy/ Region of Interest*: • Vascular/peripheral vascular • Musculoskeletal (conventional and superficial) • Small organs • Thoracic/lung • Ophthalmic • Pediatrics • Neonatal cephalic *Interventional guidance* • Free hand needle/catheter placement • Fluid drainage • Nerve block • Vascular access and biopsy	Addition of Linear Array Transducer Clinical Applications
Transducer Frequency	**Phased Array Transducer:** 1.5 – 4.5 MHz with center frequency 3Hz	**Phased Array Transducer:** 1.5 – 4.5 MHz with center frequency 3Hz		Remains unchanged
	Linear Array Transducer: 4-11 MHz with center frequency 7.5 MHz		**Linear Array Transducer** : 3-12 MHz with center frequency of 7.7 MHz	Addition of technological characteristics for Linear Array Transducer
Modes of Operation	**Phased Array Transducer:** • B-mode • M-mode • Color Doppler	**Phased Array Transducer:** • B-mode • M-mode • Color Doppler		Addition of the following modes of operation: • Pulsed-Wave (PW) Doppler • Continuous-Wave

Feature	Subject Device: Kosmos (This 510(k) Submission)	Predicate Device: Kosmos (K193518)	Reference Device: Vscan Air (K202035)	Comparison
	• Pulsed-Wave (PW) Doppler • Continuous-Wave (CW) Doppler • Combined Modes: B+M, B+CD, B+PW, and B+CW • Harmonic Imaging	• Combination Modes: B+M, B+CD • Harmonic Imaging		(CW) Doppler • Combined Modes: B+PW and B+CW
	Linear Array Transducer: • B-mode		**Linear Array Transducer:** • B-mode • Color Doppler • Combined Modes of B + CD • Harmonic Imaging	Addition of Linear Array Transducer B-mode
510(k) Track	**Phased Array Transducer:** Track 3	**Phased Array Transducer:** Track 3		Remains unchanged
	Linear Array Transducer: Track 3		**Linear Array Transducer:** Track 3	Remains unchanged
DA (Digital Auscultation) 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: 12.7 kHz		Remains unchanged
DA Filter Modes	Heart/Midrange (50 – 600 Hz)	Heart/Midrange (50 – 600 Hz)		Remains unchanged
DA Sound Amplification	Analog gain: 20 dB Digital gain: user adjustable up to 25 dB	Analog gain: 20 dB Digital gain: user adjustable up to 25 dB		Remains unchanged
DA Volume Control	Yes; 15 volume steps available	Yes; 15 volume steps available		Remains unchanged
DA Ambient Noise Reduction	Yes	Yes		Remains unchanged
DA Direct Listening	Sounds can be listened to in real time using a digital-to-analog binaural headset	Sounds can be listened to in real time using a digital-to-analog binaural headset		Remains unchanged
ECG Non-Continuous Monitoring Leads	3-lead, single-channel, user-supplied commercial electrodes	3-lead, single-channel, user-supplied commercial electrodes		Remains unchanged
ECG Anatomical Sites	Chest (torso) and Leg	Chest (torso) and Leg		Remains unchanged

Feature	Subject Device: Kosmos (This 510(k) Submission)	Predicate Device: Kosmos (K193518)	Reference Device: Vscan Air (K202035)	Comparison
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 Thor probe	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 Thor probe		Remains unchanged
DA and ECG Visualization	Sounds and ECG waveforms can be visualized and recorded on the Thor tablet with or without an internet connection	Sounds and ECG waveforms can be visualized and recorded on the Thor tablet with or without an internet connection		Remains unchanged
System Characteristics				
Dimensions and Weight	*Handheld tablet display unit (proprietary) – Kosmos Bridge* • Height: 146 mm • Width: 216mm • Depth: 59mm • Weight: 657g *Kosmos Torso Probe (Phased Array – ECG, DA, and Ultrasound)* • Height: 150mm (excluding cable (the hard plastic housing length)) • Width: 56mm • Depth: 35mm • Weight: 290 grams (with ferrite-equipped cable) • Cable dimensions: 1.8 meters *Kosmos Torso-One Probe (Phased Array – Ultrasound Only)* • *Height: 150* mm (excluding cable (the hard plastic housing length)) • Width: 56 mm • Depth: 35 mm • Weight: 275 grams (with ferrite-equipped cable) • Cable dimensions:	*Handheld tablet display unit (proprietary) – Kosmos Bridge* • Height: 146 mm • Width: 216mm • Depth: 59mm • Weight: 657g *Kosmos Torso Probe* • Height: 150mm (excluding cable (the hard plastic housing length)) • Width: 56mm • Depth: 35mm • Weight: 290 grams (with ferrite-equipped cable) • Cable dimensions: 1.8 meters	*Dimension and weight (maximum)* • Length: 131 • Width: 64 • Height: 31 • Weight: 205 +/- 3g *Linear Array Transducer* • Footprint: 40 mm x 7 mm (lens)	Addition of the following transducers: • Kosmos Torso-One (Ultrasound-Only Probe) • Kosmos Torso-One – USB (Ultrasound-Only Probe) • Kosmos Lexsa (Linear Probe)

Feature	Subject Device: Kosmos (This 510(k) Submission)	Predicate Device: Kosmos (K193518)	Reference Device: Vscan Air (K202035)	Comparison
	1.8 meters *Kosmos Torso-One Probe USB (Phased Array – Ultrasound Only)* • *Height: 150* mm (excluding cable (the hard plastic housing length)) • Width: 56 mm • Depth: 35 mm • Weight: 267 grams (with ferrite-equipped cable) • Cable dimensions: 1.5 meters *Kosmos Lexsa Probe (Linear Array)* • *Height: 150* mm (excluding cable (the hard plastic housing length)) • Width: 56 mm • Depth: 35 mm • Weight: 275 grams (with ferrite-equipped cable) • Cable dimensions: 1.8 meters			
Power Source	Mains and battery operated (rechargeable lithium ion battery)	Mains and battery operated (rechargeable lithium ion battery)		Remains unchanged
Patient Contact Materials	Probe and ECG Leadwires materials are biocompatible	Probe and ECG Leadwires are biocompatible		Remains unchanged
Ingress Protection (IP) Rating	• Kosmos Bridge: IP22 • All Probes: IPX7	• Kosmos Bridge: IP22 • Torso Probe: IPX7		Remains unchanged
DICOM	Yes	Yes		Remains unchanged
Wireless Networking	• IEEE 802.11 a/b/g/n/ac • Bluetooth 4.2 or later	• IEEE 802.11 a/b/g/n/ac • Bluetooth 4.2 or later		Remains unchanged

11. Non-Clinical Performance Data

Kosmos has been designed and evaluated to comply with the FDA-recognized consensus standards in the table below. 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.

Standards Developing Organization	Standard Designation Number and Date	Title of Standard
CISPR/CIS/B	CISPR 11:2015+ AMD1:2016+AMD2:2019 CSV Consolidated version	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
ANSI AAMI IEC	ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
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
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
ISO	10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management proce
ISO	14971:2019	Medical devices - Application of risk management to medical devices
IEC	62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes
IEC	62366-1 Edition 1.0 2015-02	Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]
ISO	15223-1 Third Edition 2016-11-01	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements

Standards Developing Organization	Standard Designation Number and Date	Title of Standard
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
NEMA	UD 2-2004 (R2009)	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3
AIM	Standard 7351731 Rev. 2.00 2017-02-23	Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields
ANSI AAMI	EC53:2013	ECG trunk cables and patient leadwires
AAMI	TIR57:2016	Principles for medical device security - Risk management.
AAMI	TIR 30:2011	A Compendium Of Processes, Materials, Test Methods, And Acceptance Criteria For Cleaning Reusable 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

The conclusions drawn from the nonclinical tests, laboratory reports and internal testing demonstrate that the Kosmos device is as safe, as effective, and performs as well as or better than the predicate device (K193518).