Emagine Solutions Technology, LLC
℅ Ms. Michelle Lott
Senior RA & QA Consultant
Lean RAQA, LLC
12602 North Summerwind Drive
MARANA AZ 85658

January 23, 2020

Re: K192170
Trade/Device Name: VistaScan™ USB Ultrasound Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: December 18, 2019
Received: December 23, 2019

Dear Ms. Lott:

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)*
K192170

Device Name
VistaScan™ USB Ultrasound Imaging System

Indications for Use *(Describe)*
The VistaScan™ USB Ultrasound Imaging System is intended for diagnostic ultrasound imaging in B mode for the following applications:
Fetal/obstetric
Gynecology
Abdominal
Pediatric
Small organ
Musculo-skeletal (conventional)
Musculo-skeletal (superficial)
Urology
Pelvic floor
Neuro-muscular
Peripheral vessel

Indications for use vary by probe type. The VistaScan™ USB Ultrasound Imaging System is indicated for Rx (prescription) use and intended for use by appropriately trained healthcare professionals such as physicians and ultrasound technologists. The VistaScan™ USB Ultrasound Imaging System is intended for use in healthcare facilities such as hospitals, clinics and facilities where ultrasound testing is performed.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

K192170 **510(k) Summary**

GENERAL INFORMATION

This 510(k) Summary is submitted in accordance with 21 CFR 807, Section 807.92.

Submitted by:

Owner's Name:	Emagine Solutions Technology, LLC
Address:	9040 S. Rita Road, Suite 1270 | Tucson, AZ 85747
Contact:	Courtney Williams
Title:	CEO
Tel:	+1 (520) 485-9905
Fax:	None
Email:	courtney.williams@emaginesolutionstech.com

Contact Person:

Name:	Michelle Lott
Title:	Senior RA & QA Consultant at Lean RAQA, LLC
Tel:	+1 (520) 275 9838
Email:	michelle@leanraqa.com

Date Prepared:	January 15, 2020
Trade Name:	VistaScan™ USB Ultrasound Imaging System
Common Name:	Diagnostic Ultrasound System and Accessories
Classification Name:	Ultrasonic pulsed echo imaging system, Diagnostic Ultrasound Transducer
Classification:	Class II
Product Code:	IYO, ITX
Regulation Number:	892.1560, 892.1570
Predicate Device(s):	Interson USB Ultrasound System, Interson Corporation. (K163443) (Primary Predicate device) Interson USB Ultrasound Probe System, Interson Corporation. (K070907)
Reference Device:	Philips Lumify (K152899)

DEVICE DESCRIPTION:

The VistaScan™ USB Ultrasound Imaging System is a self-contained portable single-mode and multiple-application ultrasound imaging system. The system comprises a series of handheld probes containing an ultrasound generator/receiver, analog to digital converter, microcontroller, control logic, USB 2.0 interface, and software-based controls offering B operating mode, parameter controls, and recording functions. The selection of transducers offered with the system permit a wide range of clinical applications including Fetal/Obstetric, Abdominal, Pediatric, Small Organ, Muscular-skeletal, Urology, Gynecology, Pelvic Floor, Neuromuscular, and Peripheral Vessel.

The initial operational settings for each transducer are preprogrammed in the system. User-customized parameter settings for each transducer may be set by the operator within a specific range which is controlled by the transducer hardware/firmware and stored for recall as needed via the system control panel. Customization includes transmit power, images controls selection, and Time Gain Compensation (TGC). Controls are also provided to select display format and to utilize the Cine function.

The VistaScan™ USB Ultrasound Imaging System is a B-Mode scanner and supports a wide variety of applications. It is an ultrasound scanner providing high resolution and high penetration performance. Probes are supported in frequencies from 2.5 MHz to 10.0 MHz. The product family uses non-array, curved, and flat linear array transducers and includes two General Purpose (GP) probes and a Small Parts (SP) probe. The probes can be connected to a USB 2.0 port (micro USB and USB-C).

System Components:

- Android™ based device operating VistaScan™ application
- Transducer GP-3.5
- Transducer GP-C01
- Transducer SP-L01

Supported Hardware

The VistaScan™ USB Ultrasound Imaging System has been verified and validated on the Samsung Galaxy S4 Tablet using the Android software Operating System (OS). Device safety and performance cannot be assured when using other computing hardware which utilizes the Android OS. Computing hardware other than the Samsung Galaxy S4 Tablet using the Android software Operating System (OS) is not supported and should not be used with the VistaScan USB Ultrasound Imaging System.

Automated Safety/Performance Checks

The VistaScan™ USB Ultrasound Imaging System includes several automated safety/performance checks to verify that the USB ultrasound probe is functioning properly prior to use. These automated performance checks include:

- System Initialize
- Hardware Initialize
- Hardware Check
- Probe ID Code Read
- Setup Control

INTENDED USE / INDICATIONS FOR USE:

The VistaScan™ USB Ultrasound Imaging device is intended for diagnostic ultrasound imaging in B mode for the following applications:

- Fetal/obstetric
- Gynecology
- Abdominal
- Pediatric
- Small Organ
- Musculo-skeletal (conventional)
- Musculo-skeletal (superficial)
- Urology
- Pelvic Floor
- Neuro-muscular
- Peripheral Vessel

Indications for use vary by probe type. The VistaScan™ USB Ultrasound Imaging System is indicated for Rx (prescription) use and intended for use by appropriately trained healthcare professionals such as physicians and ultrasound technologists. The VistaScan™ USB Ultrasound Imaging System is intended for use in healthcare facilities such as hospitals, clinics and facilities where ultrasound testing is performed.

PRODUCT MODELS:

Table 1: Common Applications of Transducer Models

Model	Track	Common Applications
Transducer Model GP 3.5 MHz	1	Fetal, Abdominal, Small Organ
Transducer Model GP-C01	3	Fetal/Obstetric, Abdominal, Pelvic Floor, Urology, Musculoskeletal, Small Organs, Neuromuscular
Transducer Model SP-L01	3	Pediatric, Small Organs, Peripheral Vessel, Pelvic Floor

LABELING AND TECHNOLOGICAL CHARACTERISTICS COMPARISON:

Both the proposed VistaScan™ USB Ultrasound Imaging System and the predicate devices are provided nonsterile. They use similar packaging systems except for adapted product documentation (instructions for use in package labeling). The proposed VistaScan™ device has an identical intended use for B mode imaging, and similar technology characteristics to the currently marketed Interson USB Ultrasound Probe System (K070907, K163443). Technological differences are limited to the software operating system. The VistaScan™ device uses a commercially available electronic mobile device with an Android-based operating system, while the predicate Interson USB Ultrasound Probe System (K070907, K163443) device uses a proprietary Windows-based imaging system. All other technological features are substantially equivalent to the Interson USB Ultrasound Probe System (K070907, K163443). The reference device was selected as a point of comparison for the software operating system. Both the

VistaScan™ device and the reference device, Philips Lumify (K152899), use an Android based operating system.

Table 2: Predicate Comparison Table

Device Features	Subject Device: VistaScan™ USB Ultrasound Imaging System	Primary Predicate: Interson Ultrasound System: K163443	Secondary Predicate: Interson Ultrasound System K070907	Reference Device: Philips Lumify K152899
Intended Use	Diagnostic ultrasound imaging in B mode.	Diagnostic ultrasound imaging in B, color Doppler and Combined (B + Color) modes.	Diagnostic ultrasound imaging in B mode (all transducers), A mode (ophthalmic)	Diagnostic ultrasound imaging in B, color Doppler, and Combined (B + Color) modes.
Indications for Use	Indicated for diagnostic ultrasound imaging in specified applications	Indicated for diagnostic ultrasound imaging and fluid flow analysis in specified applications	Indicated for diagnostic ultrasound imaging in specified applications	Indicated for diagnostic ultrasound imaging and fluid flow analysis in specified applications
Array Geometry	Non-Array Curved and linear	Curved and linear	Non-Array	Curved and linear
Mechanics	Mechanical Solid State	Solid State	Mechanical	Solid State
Software platform	Commercial off-the-shelf operating system (Android)	Commercial off-the-shelf operating system (Windows)	Commercial off-the-shelf operating system (Windows)	Commercial off-the-shelf operating system (Android)
Software control	Standalone	Standalone	Standalone	Standalone
Measurement function	2D measurement	2D measurement and area measurement	2D measurement tool	2D measurement tool
Wireless networking	Not supported	Not supported	Not supported	Supported
Connector	USB	USB	USB	USB

NON-CLINICAL PERFORMANCE TESTING

The VistaScan™ USB Ultrasound Imaging System was generally evaluated against relevant requirements in *Marketing Clearance of Diagnostic Ultrasound Systems and Transducers: Guidance for Industry and Food and Drug Administration Staff*, June 27, 2019.

- Acoustic Output
- Clinical measurement accuracy and system sensitivity
- Thermal, mechanical, and electrical safety
- Patient -contacting materials
- Cleaning, disinfection, sterilization, and pyrogenicity
- Software

Verification testing was conducted against predetermined acceptance criteria and recognized standards[1] to show that the subject device performs functions equivalent to the predicate device. VistaScan™ successfully passed verification testing. The results support substantial equivalence to the predicate device and demonstrate that is safe and effective for its intended use.

Electrical Safety / Electromagnetic Compatibility

Evaluation per standard IEC 60601 1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) and IEC/EN 60601-1-2:2014 was performed for use of the transducer with a specific computer model (HP Netbook). Use of alternate USB 2.0 compatible computer hardware requires verification by the end user. Further information is provided in the Instructions for Use.

Standards Conformity

The VistaScan™ USB Ultrasound Imaging System references the following FDA recognized standards:

Standard Number/FDA Recognition#	Standard Name
IEC 60601 1: 2005 + CORR. 1 (2006) + CORR. 2 (2007), FDA Recognition#: 19-4	Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
IEC/EN 60601-1-2:2014 4th Ed. FDA Recognition#: 19-8	Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-2-37:2007 FDA Recognition#: 12-293	Medical electrical equipment -Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

ANIMAL AND CLINICAL TESTING

VistaScan™ USB Ultrasound Imaging System introduces no new indication for use, modes, features, or technologies relative to the predicate devices that require animal or clinical testing. The clinical safety and effectiveness of ultrasound systems with these characteristics are well accepted for both predicate and subject devices.

CONCLUSION OF COMPARISON

The VistaScan™ USB Ultrasound Imaging System device and its predicate device are technologically similar. The devices are identical in their use of probes, and similar in design, materials, and technological characteristics. The packaging and labeling has been designed to provide sufficient information to the user to ensure the safe and effective use of the proposed device. Furthermore, the proposed device is comparable to the reference device which was cleared for the same intended use for B mode operation, the same indication for use, and utilizes the same operating platform. The proposed device does not raise substantial new questions of safety or effectiveness. Therefore, the proposed device (VistaScan™ USB Ultrasound Imaging System) is determined to be substantially equivalent to the predicate device.

[1] Electrical Safety and EMC standards are applied by 'right of reference'.