Section 5 - 510(k) Summary

K102153

JAN 20 2011

Submitter: Mobisante, Inc.
14035 NE 85th CT
Redmond, WA 98052

Contact Person: Sailesh Chutani
President and CEO

Telephone: (650) 804-5421

Date Prepared: July 30, 2010

Device Trade Name: MobiUS Ultrasound Imaging System

Device Common Name: Diagnostic Ultrasound System and Accessories
Ultrasound Pulsed Echo Imaging System
Diagnostic Ultrasound Transducer

Classification Number and Product Code: §21CFR 892.1560 90-IYO
§21CFR 892.1570 90-ITX

Device Classification: Class II

Predicate Device(s):

DEVICE NAME	ACCESSION NUMBER(S)
INTERSON USB Ultrasound Probe System	K070907
GE VScan Diagnostic Ultrasound System	K092756
Signos Personal Ultrasound	K090505

Intended Use:

The MobiUS Ultrasound Imaging System is indicated for ultrasound imaging, measurement and analysis of the human body for the following clinical applications: fetal/OB, abdominal, cardiac, pelvic, pediatric, musculoskeletal, and peripheral vessel imaging. Its compact size, portability and user interface enable it for use in primary care and special care areas.

Device Description:

The MobiUS Ultrasound Imaging System is a compact, portable ultrasound imaging system consisting of a handheld ultrasound probe, cable, host computer and user interface. The ultrasound probe and cable is one of the five models of the INTERSON USB Ultrasound Imaging Probe, ranging from 3.5 MHz to 12.0 MHz. The probes consist of a single-element mechanical sector scanner that contains the ultrasound generator and receiver, analog-to-digital converter, microcontroller, control logic, USB 2.0 interface and control within the hand piece. It has a push button control to activate scanning. The probe is connected via a USB cable to a host computer. The host computer comes preloaded with the MobiUS software which utilizes an icon touch-based user interface. The software enables ultrasound image capture and review, image controls for near, mid, and far gain, as well as image intensity and contrast, linear measurement, storage and transmission of images and videos. The MobiUS Ultrasound Imaging System allows the user to image in real-time and review cine or freeze-frame images on the screen in B-Mode scan format.

Technological Characteristics:

The Mobisante MobiUS Ultrasound Imaging System operates in the same manner as the identified predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as 2D images of anatomic structures within the body. All systems allow for the measurement of structures to aid in diagnosis.

Basis for Substantial Equivalence:

The MobiUS Ultrasound Imaging System is substantially equivalent to the identified predicate devices currently cleared for market with respect to intended use, principles of operation, technological characteristics and safety features. The system has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Sailesh Chutani
President and CEO
MOBISANTE, INC.
14035 NE 85th CT
REDMOND WA 98052

JAN 20 2011

Re: K102153
Trade/Device Name: MobiUS Ultrasound Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: January 12, 2011
Received: January 12, 2011

Dear Mr. Chutani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the MobiUS Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number

MV 12.0 MHz Mechanical Sector Probe
EC 7.5 MHz Mechanical Sector Probe
SR 7.5 MHz Mechanical Sector Probe
GP 5.0 MHz Mechanical Sector Probe
GP 3.5 MHz Mechanical Sector Probe

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. 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); 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.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Section 4 - Indications for Use Statement

510(k) Number (if known): K102153

Device Name: MobiUS Ultrasound Imaging System

Indications for Use:

The MobiUS Ultrasound Imaging System is indicated for ultrasound imaging, measurement and analysis of the human body for the following clinical applications: fetal/OB, abdominal, cardiac, pelvic, pediatric, musculoskeletal, and peripheral vessel imaging. Its compact size, portability and user interface enable it for use in primary care and special care areas.

Please refer to the following diagnostic ultrasound indications for use forms for specific imaging modes and applications.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102153

Diagnostic Ultrasound Indications for Use

510(k) Number:

System: MobiUS Ultrasound Imaging System with INTERSON USB Ultrasound Probe System

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	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N						Note 3
	Abdominal	N						Note 1 Note 3
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N						Note 3
	Small Organ (Specify)	N						Note 3 Note 2
	Neonatal Cephalic	N						
	Adult Cephalic							
	Trans-rectal	N						Note 3
	Trans-vaginal	N						Note 3
	Trans-urethral							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**	N						
	Musculo-skeletal **(Superficial)**	N						
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	N						
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N						
	Other (Specify)							

N=New Indication

Note 1: Abdominal, Solid organs, aneurysms

Note 2: Small organ, breast, thyroid, testes

Note 3: Includes imaging for guidance of biopsy

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~~concurrence of CDRH, Office of Device Evaluation~~ (Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Prescription Use: YES

Per 21 CFR 801. 109

510K_____ 510(k) Number_____

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102153

Diagnostic Ultrasound Indications for Use

510(k) Number:

System: MobiUS Ultrasound Imaging System

Transducer: **INTERSON USB Ultrasound Probe System**
MV 12.0 MHz Mechanical Sector Probe

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	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)	P						Note 2 Note 3
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	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	P						Note 3
	Other (Specify)							

P=Previously Cleared by INTERSON Corporation: K070907

Note 2: Small organ, breast, thyroid, testes

Note 3: Includes imaging for guidance of biopsy

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concurrence of CDRH, Office of Device Evaluation

Prescription Use: YES
Per 21 CFR 801. 109

510(k) Number_____

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102153

Diagnostic Ultrasound Indications for Use

510(k) Number:

System: MobiUS Ultrasound Imaging System

Transducer: INTERSON USB Ultrasound Probe System
EC 7.5 MHz Mechanical Sector Probe

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	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P						Note 3
	Trans-vaginal	P						Note 3
	Trans-urethral							
	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							
	Other (Specify)							

P=Previously Cleared by INTERSON Corporation: K070907

Note 3: Includes imaging for guidance of biopsy

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concurrence of CDRH, Office of Device Evaluation

Prescription Use: YES
Per 21 CFR 801. 109

510(k) Number_____

Diagnostic Ultrasound Indications for Use

510(k) Number:

System: MobiUS Ultrasound Imaging System

Transducer: **INTERSON USB Ultrasound Probe System**
SR 7.5 MHz Mechanical Sector Probe

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	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P						Note 3
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)	P						
	Neonatal Cephalic	P						
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	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	P						
	Other (Specify)							

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Note 3: Includes imaging for guidance of biopsy

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concurrence of CDRH, Office of Device Evaluation

Prescription Use: YES
Per 21 CFR 801. 109

510(k) Number_____

Mary S. Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102153

Diagnostic Ultrasound Indications for Use

510(k) Number:

System: MobiUS Ultrasound Imaging System

Transducer: **INTERSON USB Ultrasound Probe System**
GP 5.0 MHz Mechanical Sector Probe

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	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P						
	Abdominal	P						Note 3
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)	P						Note 2
	Neonatal Cephalic	P						
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	P						
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

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Note 2: Small organ, breast, thyroid, testes

Note 3: Includes imaging for guidance of biopsy

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concurrence of CDRH, Office of Device Evaluation

Prescription Use: YES
Per 21 CFR 801. 109

510(k) Number_____

Diagnostic Ultrasound Indications for Use

510(k) Number:

System: MobiUS Ultrasound Imaging System

Transducer: INTERSON USB Ultrasound Probe System
GP 3.5 MHz Mechanical Sector Probe

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	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P						
	Abdominal	P						Note 3
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)	P						Note 2
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	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							
	Other (Specify)							

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Note 2: Small organ, breast, thyroid, testes

Note 3: Includes imaging for guidance of biopsy

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Prescription Use: YES
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