K110447

510(k) Summary

MAY 2 7 2011

EchoInsight™

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, *Content and Format of a 510(k) Summary.*

Submitted By:
Ultrasound Medical Devices, Inc., dba Epsilon Imaging, Inc.
3917 Research Park Drive, Suite B7
Ann Arbor, Michigan 48108

Contact Person:
Paul Kortesoja
Director of Operations
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Date Prepared:
February 14, 2011

Proprietary Name:
EchoInsight™

Common/ Usual Name:
Image Processing System

Classification Name:
21 CFR §892.2050 Picture archiving and communications system
Product Code LLZ-Image Processing System

Predicate Device:
syngo US Workplace, K091286 (VVI component of Clinical Application Package[CAP])

Device Description:
The EchoInsight™ software system enables the production and visualization of 2D tissue motion measurements (including tissue velocities, strains, strain rates) and cardiac structural measurement information derived from tracking speckle in tissue regions visualized in any B-mode (including harmonic) imagery loops as captured by most commercial ultrasound systems.

The EchoInsight™ software system has been designed to ingest and process ultrasound imagery stored in files with content organized and encoded in conformance to the following the following standards:

- NEMA PS3 (3.3, 3.5, 3.6, 3.10): Digital Imaging and Communications in Medicine (DICOM), 2008.
- ISO/IEC 10918-1:1994-02: Information technology – Digital compression and coding of continuous-tone still images – Requirements and guidelines (JPEG standard), 1994.
- ISO/IEC 15444-1:2004: Information technology – JPEG 2000 image coding system: Core coding system, 2004.

Intended Uses:
EchoInsight™ is intended for use by or on the order of a qualified physician for analysis of ultrasound imaging of the human heart. Cardiac (adult and pediatric) applications using B-mode (including harmonic) imaging are supported. The system provides image data analysis applications that supply information on cardiac structure and motion.

Technological Comparison to Predicate Devices:
EchoInsight™ is substantially equivalent to the Siemens VVI product already cleared for introduction into interstate commerce as part of K091286, syngo US Workplace. The new and predicate devices both provide methods for determination of tissue motion, strain, and strain rate for cardiac structures based on speckle tracking techniques. The new and predicate devices provide similar image and information visualization capabilities. Both utilize B-mode ultrasound imagery from other vendor as well as same vendor ultrasound scanning devices as input.

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MAY 27 2011

Ultrasound Medical Devices, Inc.
c/o Paul Kortesoja
Director of Operations
3917 Research Park Drive, Suite B7
ANN ARBOR MI 48108

Re: K110447
Trade Name: EchoInsight
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 3, 2011
Received: May 4, 2011

Dear Mr. Kortesoja:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) 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 the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

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

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: EchoInsight™

Indications for Use:

Intended for use by or on the order of a qualified physician for analysis of ultrasound imaging of the human heart. Cardiac (adult and pediatric) applications using B-mode (including harmonic) imaging are supported. The system provides image data analysis applications that supply information on cardiac structure and motion.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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

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