510(k) Summary

Ultra DCI Model 5000

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 dba Epsilon Imaging, Inc.
3917 Research Park Drive, Suite B7
Ann Arbor, Michigan 48108

Contact Person:
Paul Kortesoja
Director of Operations
Phone: (734) 369-5102
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Date Prepared:
February 3, 2010

Proprietary Name:
Ultra DCI Model 5000

Common/ Usual Name:
Diagnostic Ultrasound System

Classification Name:
21 CFR §892.1560 Ultrasonic Pulsed Echo Imaging System (Product Code IYO)
21 CFR §892.1570 Diagnostic Ultrasound Transducer (Product Code ITX)

Predicate Devices:
K022567 cleared as the Sequoia Diagnostic Ultrasound System Signature II and K024236 cleared as the Ultrasound Scanner Type 2400.

Device Description:
The Ultra DCI Model 5000 is a general purpose, mobile, software-controlled, diagnostic ultrasound system designed to provide the user with the ability to collect standard 2D brightness mode (B-mode) echocardiographic views of the heart, visualize these views and store the collected data for later visualization. The device includes a 4-lead electrocardiograpic (ECG) module and patient connections to collect and display a single ECG trace (PQRST wave) along with the B-mode imagery.

The Ultra DCI Model 5000 has been designed to meet the following product safety standards:

- NEMA UD-2 Measurement Standard (1998)
- IEC 60601-1:1988+A1:1991+A2:1995, *Medical electrical equipment* – Part 1: *General requirements for safety.*

- IEC 60601-1-2:2001+A1:2004 *Medical electrical equipment* – Part 1-2: *General requirements for safety* – Collateral standard: *Electromagnetic compatibility – Requirements and tests*
- IEC 60601-2-37 (2004), (2005) Amendment 2, *Medical Electrical Equipment*— Part 2–37: *Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment.*

Intended Uses:
The Ultra DCI 5000 System is intended for use by, or on the order of, a qualified physician for ultrasound imaging of the human heart. The cardiac (adult and pediatric) application using B-mode imaging is supported.

Technological Comparison to Predicate Devices:
The Ultra DCI Model 5000 is substantially equivalent to products that are already cleared for USA distribution, K022567 and K024236. The new and predicate devices transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen displays of anatomic structures within the body. All devices utilize B-mode imaging and all are indicated for cardiac use.

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 21 2010

Mr. Paul Kortesoja
Director of Operations
Ultrasound Medical Devices, Inc. dba Epsilon Imaging, Inc.
3917 Research Park Drive, Suite B7
ANN ARBOR MI 48108

Re: K100363
Trade/Device Name: Ultra DCI Model 5000
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO
Dated: April 9, 2010
Received: April 12, 2010

Dear Mr. Kortesoja:

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 Ultra DCI Model 5000, as described in your premarket notification:

Transducer Model Number

U000004

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,

Donald St. Pierre
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K100363

Device Name: Ultra DCI Model 5000

Indications for Use:

The Ultra DCI Model 5000 is indicated for use by, or on the order of, a qualified physician for ultrasound imaging of the human heart. The cardiac (adult and pediatric) application using Bmode imaging is supported.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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

510(k) Number K100363

EPSILON IMAGING

RE: K100363
ATTACHMENT 2 – Indication for Use Table – System

System: Ultra DCI Model 5000

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

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

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

510K K100363

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EPSILON IMAGING

RE: K100363
ATTACHMENT 3 – Indication for Use Table – Transducer

Transducer: U000004

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

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

(Division Sign-Off)
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510K K100363

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