K013848

APR - 8 2002

2.4 510(k) Summary

510(k) Summary
U-Systems Ultrasound System
U-Systems INC.

Prepared November 15, 2001

Product Name: U-2000 Ultrasound System

Manufacturer: U-Systems Inc.

Generic Name: Diagnostic Ultrasound System

Classification Name: Ultrasound Imaging System and Transducers (Class II); Classification codes:

IYO	892.1560	System, Imaging Pulsed Echo, Ultrasonic
IYN	892.1550	System, Imaging, Pulsed Doppler, Ultrasonic
ITX	892.1570	Transducer, Ultrasonic, Diagnostic

Contact Person: Sheila W. Pickering Ph.D.
2081 Longden Circle
Los Altos, California 94024
Telephone/Fax 650 969 6114
e-mail: swpraqa@aol.com

A. Legally Marketed Predicate Device
The modification to the U-2000 software is substantially equivalent to the Echotech 3D Freescan with regard to features, specifications, and intended use.

B. Device Description
The modified U-2000 software provides the capability for the acquisition, analysis, storage and retrieval of digital 3D ultrasound image data sets and multiplaner reformatting capabilities.

C. Intended Use
The modified U-2000 is indicated for acquisition of related sets of 2D ultrasound images and 3 dimensional reconstruction of diagnostic ultrasound images. It is intended to acquire, analyze, store, and retrieve digital ultrasound images for computerized 3 dimensional image processing.

D. Substantial Equivalence
The U-2000 is substantially equivalent to the Echotech 3D Freescan, which is currently in commercial distribution.

E. Performance Data

The modified software has been validated according to the company's software quality assurance procedures, as certified in the original 510(k) Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2002

Sheila W. Pickering, Ph.D.
Regulatory Affairs Consultant
U-Systems, Inc.
2081 Longden Circle
LOS ALTOS CA 94024

Re: K013848
Trade Name: USI-2000 Diagnostic Ultrasound System, Modified Software
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Product Code: 90 IYN
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Product Code: 90 IYO
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Product Code: 90 ITX
Regulatory Class: II
Dated: February 27, 2002
Received: March 1, 2002

Dear Dr. Pickering:

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 USI-2000 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

7.5 MHz
10 MHz

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 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); 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 contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97).

Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use

510(k) Number(s): N/A

Device Name: USI-2000
Diagnostic Ultrasound Pulsed Echo System
Diagnostic Ultrasound Pulsed Doppler Imaging System

Intended Use:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)*	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N		Note 1	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)		N	N	N		N	N		Note 1	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Laproscopic										
Peripheral Vascular		N	N	N		N	N		Note 1	
Musculo-skeletal Conventional		N	N	N		N	N		Note 1	
Musculo-skeletal Superficial										

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Amplitude Doppler; B/Color Doppler/PWD and B/Amplitude Doppler/PWD

N = new indication
P = previously cleared by FDA

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033848

Prescription Use ✓

Diagnostic Ultrasound Indications for Use

510(k) Number: N/A

Device Name: 7.5 MHz Transducer
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)*	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N		Note 1	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)		N	N	N		N	N		Note 1	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Laproscopic										
Peripheral Vascular		N	N	N		N	N		Note 1	
Musculo-skeletal Conventional		N	N	N		N	N		Note 1	
Musculo-skeletal Superficial										

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Amplitude Doppler; B/Color Doppler/PWD and B/Amplitude Doppler/PWD

N = new indication
P = previously cleared by FDA

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Prescription Use ✓

Nancy C Brogdon 023
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number 1/01/28/08

Diagnostic Ultrasound Indications for Use

510(k) Number: N/A

Device Name: 10 MHz Transducer
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)*	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N		Note 1	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)		N	N	N		N	N		Note 1	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Laproscopic										
Peripheral Vascular		N	N	N		N	N		Note 1	
Musculo-skeletal Conventional		N	N	N		N	N		Note 1	
Musculo-skeletal Superficial										

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Amplitude Doppler; B/Color Doppler/PWD and B/Amplitude Doppler/PWD

N = new indication
P = previously cleared by FDA

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon 024
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013848

Prescription Use ✓