DEC 2 4 2002

K022617

510(k) Summary
U-Systems Ultrasound System
U-Systems INC.
Prepared November 1, 2002

Product Name: USI-2000 Ultrasound System with automated scanning accessory

Manufacturer: U-Systems Inc.

Generic Name: Diagnostic Ultrasound System accessory

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 USI-2000 is substantially equivalent to the LABSONICS Ultrasound Breast Scanner manufactured by LABSONICS, Inc. and the Sonopsy LA System manufactured by NeoVision, Inc., which have been placed in commercial distribution. The intended use and the technological characteristics of the modification are the same as the predicate devices.

B. Device Description
The modified USI-2000 includes an accessory for use with the existing diagnostic ultrasound system. The accessory is intended to provide automated data acquisition of ultrasound breast images. Imaging is based on B-mode ultrasound technique using electronic focusing. High-gain electronics recovers the reflected ultrasound signal which is displayed on a computer screen. The accessory includes a mechanical apparatus for breast image acquisition, a video monitor to display the images, and related software. The patient stands next to system and mammography-like plates compress the breast. Tissue is electronically and mechanically scanned using linear array transducer through thin layer of water and sono-lucent film.

C. Intended Use
The USI-2000 Diagnostic Ultrasound System is being modified to include an accessory for use with the existing diagnostic ultrasound system. The device is indicated for use as an adjunct to mammography for B-mode ultrasonic imaging of a patient's breast when used with an automatic scanning linear array transducer. Automatic scanning obtains multiple, sequential two-dimensional images which can be compiled into a three-dimensional data set for viewing in three planes.

D. Substantial Equivalence

The USI-2000 is substantially equivalent to the to the LABSONICS Ultrasound Breast Scanner manufactured by LABSONICS, Inc. and the Sonopsy LA System manufactured by NeoVision, Inc. with regard to intended use and technological characteristics.

E. Performance Data

The USI-2000 accessory's performance has been validated according to the company's quality assurance procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 4 2002

U-Systems, Inc.
% Ms. Sheila Pickering, Ph.D.
2081 Longden Circle
LOS ALTOS CA 94024

Re: K022517
Trade Name: USI-2000 Ultrasound System with Automated Scanning Accessory
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYN, IYO, and ITX
Dated: November 1, 2002
Received: November 5, 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 Ultrasound System, as described in your premarket notification:

Transducer Model Number

7.5 MHz
10 MHz
L9.5 (XW) 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 determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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,

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

Enclosure(s)

1.1 Diagnostic Ultrasound Indications for Use

510(k) Number(s): K022517

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

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		P	P	P		P	P		Note !	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)		P	P	P		P	P		Note 1	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Laproscopic										
Peripheral Vascular		P	P	P		P	P		Note 1	
Musculo-skeletal Conventional		P	P	P		P	P		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

The USI Needle Guide accessory is intended for small parts use for breast biopsy.
The USI Horizon Automated Scanning accessory is intended for breast examinations.

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)

Prescription Use ✓

(Division Sign-Off) 063
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022517

Diagnostic Ultrasound Indications for Use

510(k) Number: K022517

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	P	P	P			P	P	Note 1		
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)	P	P	P			P	P	Note 1		
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Laproscopic										
Peripheral Vascular	P	P	P			P	P	Note 1		
Musculo-skeletal Conventional	P	P	P			P	P	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

The USI Needle Guide accessory is intended for small parts use for breast biopsy.
The USI Horizon Automated Scanning accessory is intended for breast examinations.

N = new indication
P = previously cleared by FDA

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(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022517

Prescription Use ✓

Diagnostic Ultrasound Indications for Use

510(k) Number: K022517

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		P	P	P		P	P		Note 1	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)		P	P	P		P	P		Note 1	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Laproscopic										
Peripheral Vascular		P	P	P		P	P		Note 1	
Musculo-skeletal Conventional		P	P	P		P	P		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

The USI Needle Guide accessory is intended for small parts use for breast biopsy.
The USI Horizon Automated Scanning accessory is intended for breast examinations.

N = new indication
P = previously cleared by FDA

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(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022517

Prescription Use ✓

010

Diagnostic Ultrasound Indications for Use

510(k) Number: K022517

Device Name: L 9.5 (XW) 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		P								
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)		P								
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Laproscopic										
Peripheral Vascular										
Musculo-skeletal Conventional										
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

The USI Needle Guide accessory is intended for small parts use for breast biopsy.
The USI Horizon Automated Scanning accessory is intended for breast examinations.

N = new indication
P = previously cleared by FDA

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(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022517

Prescription Use ✓

011

FDA Submission Cover Sheet

510(k) Number (if known): K022517

Device Name: Modification: U-Systems USI-2000 Diagnostic Ultrasound System

Indications For Use:
The USI-2000 Diagnostic Ultrasound System is being modified to include an accessory for use with the existing diagnostic ultrasound system. The device is indicated for use as an adjunct to mammography for B-mode ultrasonic imaging of a patient's breast when used with an automatic scanning linear array transducer. Imaging is based on B-mode ultrasound technique using electronic focusing. High-gain electronics recovers reflected ultrasound signals displayed on a computer screen. Automatic scanning obtains multiple, sequential two-dimensional images, which can be compiled into a three-dimensional data set for viewing in three planes.

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_____ Concurrence Of CDRH, Office Of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21CFR 801)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022517

012