K080930

AUG - 7 2008

# 510(k) Summary

## Modified Automated Breast Ultrasound System (ABUS)

Prepared April 1, 2008

**Product Name:** Automated Breast Ultrasound System (ABUS)

**Manufacturer:**
U-Systems Inc.
110 Rose Orchard Way
San Jose, CA 95134
Telephone (408) 750-0777
Fax (408) 571-0771

**Common Name:** Diagnostic Ultrasound System

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

**Classification Codes:** IYO, 892.1560, System, Imaging Pulsed Echo, Ultrasonic
ITX, 892.1570, Transducer, Ultrasonic, Diagnostic

**Contact Person:**
Lisa Scott
110 Rose Orchard Way
San Jose, California 95134
Telephone 408-750-1373
e-mail: lscott@u-systems.com

### A. Legally Marketed Predicate Device

The Company believes that the modified ABUS is substantially equivalent to the previously cleared *U-Systems - ABUS* (K052355), as well as the *Siemens - Antares* DUS (K023720).

The intended use and the technological characteristics of the device are the same as the predicate devices.

### B. Device Description

The ABUS system with automated ultrasound imaging of the breast, gives the radiologist a cost-effective solution for reviewing the ultrasound images with the corresponding mammogram.

The modification to the sponsor's predicate device consists of the addition of the accessory of a conventional handheld ultrasound transducer, and modification to the software to control the new transducer.

## C. Intended Use

General Indication for Use
An ultrasound pulsed echo imaging system is intended to project a pulsed sound beam into body tissue to determine the depth of location of the tissue interfaces and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts and accessories.

Specific Indications for Use
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 or a handheld transducer. The device is not intended to be used as a replacement for screening mammography.

## D. Substantial Equivalence

The ABUS System modification is substantially equivalent to the sponsor's original ABUS device (K052355) as well as the Siemens Antares DUS (K023720. The intended use and the technological characteristics of the device are the same as the predicate devices.

## E. Performance data

The ABUS System will successfully complete integration testing, beta testing, and verification and validation prior to market release.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2008

Ms. Lisa Scott
Vice President, Regulatory Affairs and Quality Assurance
U-Systems, Inc.
110 Rose Orchard Way
SAN JOSE CA 95134

Re: K080930
Trade/Device Name: Automated Breast Ultrasound System (ABUS)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: June 27, 2008
Received: June 30, 2008

Dear Ms. Scott:

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 Automated Breast Ultrasound System (ABUS), as described in your premarket notification:

Transducer Model Number

L9-5XW MHz
L10-5XW MHz
L12-6 MHz
L15-6 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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

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)

**Indications for Use**

510(k) Number: _____

Device Name: Automated Breast Ultrasound System (ABUS)

General Indication for Use:
An ultrasound pulsed echo imaging system is intended to project a pulsed sound beam into body tissue to determine the depth of location of the tissue interfaces and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts and accessories.

Specific Indications for Use:
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 or a handheld transducer. The device is not intended to be used as a replacement for screening mammography.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

| Prescription Use ☒ | OR | Over-The-Counter Use |
|---|---|---|
| (Part 21 CFR § 801 Subpart D) | | (Part 21 CFR § 801 Subpart C) |

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080930

## Diagnostic Ultrasound Indications for Use Forms

510(k) Number(s):
Device Name: Automated Breast Ultrasound System (ABUS)

Intended Use: Diagnostic ultrasound imaging 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 | | | | | | | | | | |
| Intraoperative (specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (breast, thyroid, testes) | | P | | | | | | | | P Note 1,2 |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Tranesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Laproscopic | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |

Note 1: Harmonic Imaging
Note 2: Spatial Compounding

P = previously cleared by FDA

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Neurological Devices
510(k) Number K080930

## Diagnostic Ultrasound Indications for Use

510(k) Number: _____

Device Name: L9-5XW MHz Transducer (automated scanner)
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging 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 | | | | | | | | | | |
| Intraoperative (specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (breast, thyroid, testes) | | P | | | | | | | | P Note 1,2 |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Tranesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Laproscopic | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |

Note 1: Harmonic Imaging
Note 2: Spatial Compounding

P = previously cleared by FDA

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(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K080930

## Diagnostic Ultrasound Indications for Use

510(k) Number: _____

Device Name: L10-5XW MHz Transducer (automated scanner)
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging 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 | | | | | | | | | | |
| Intraoperative (specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (breast, thyroid, testes) | | P | | | | | | | | P Note 1,2 |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Tranesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Laproscopic | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |

Note 1: Harmonic Imaging
Note 2: Spatial Compounding

P = previously cleared by FDA

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Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K080930

## Diagnostic Ultrasound Indications for Use

510(k) Number: _____

Device Name: L12-6 MHz Transducer (automated scanner)
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging 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 | | | | | | | | | | |
| Intraoperative (specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (breast, thyroid, testes) | | P | | | | | | | | P Note 1 &2 |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Tranesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Laproscopic | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |

Note 1: Harmonic Imaging
Note 2: Spatial Compounding

P = previously cleared by FDA

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Division of Reproductive, Abdominal and
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510(k) Number K080930

## Diagnostic Ultrasound Indications for Use

510(k) Number: _____

Device Name: L15-6 MHz Transducer (handheld probe)
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging 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 | | | | | | | | | | |
| Intraoperative (specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (breast, thyroid, testes) | | N | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Tranesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Laproscopic | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |

N = new indication

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