K022153

AUG 1 5 2002

DIAGNOSTIC ULTRASOUND

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) Submitter's name, address, telephone number, contact person:

Russ Garrison
Senior Vice President, Operations
Diagnostic Ultrasound Corporation
21222 30th Drive SE, Suite 120
Bothell, WA 98021

Phone: (425) 867-1348 x1350

E-mail: rgarrison@dxu.com

Date prepared: August 1, 2002

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/ Usual Name

Diagnostic Ultrasound System with Accessories

Proprietary Name

BladderScan™ BVI 6100

Classification Names

Ultrasonic Pulsed Echo Imaging System (892.1560; 90-IYO)
Diagnostic Ultrasound Transducer (892.1570; 90-ITX)

3) Identification of the predicate or legally marketed device:

Diagnostic Ultrasound believes that the BVI 6100 System is substantially equivalent to the previously cleared Diagnostic Ultrasound BladderManager™ BVI 5000 System (K955850), Diagnostic Ultrasound BladderScan™ BVI 2500 System (K915436), and the SonoSite™ Hand-Carried Ultrasound System (K990806).

4) Device Description:

The BladderScan™ BVI 6100 Ultrasound System is a hand-held, battery-powered, software-controlled ultrasound system used to acquire and display real-time B-mode images of the bladder. The System is intended to non-invasively monitor bladder volume on an intermittent basis. The System is an effective, low cost, simple option for use in a clinical hospital or nursing home setting or for home use under medical supervision.

The BVI 6100 System is designed to comply with the standards listed below.

- EN 60601-1:1997
- EN 60601-1-1:1993
- EN 60601-1-2:1998
- EN 60601-2-37:2001
- CAN/CSA C22.2, No. 601.1 – M90
- UL 2601-1:1999
- IEC 61000-4-2:1999
- IEC 61000-4-3:1997
- IEC 61000-4-4:1995
- IEC 61000-4-5:1999
- CEI/IEC 61157:1992
- CISPR11:1997
- *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.* American Institute of Ultrasound in Medicine, 1998.
- *Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment: A Standard for How Manufacturers Should Specify Acoustic Output Data*, American Institute of Ultrasound in Medicine, 1998.
- Medical Ultrasound Safety, American Institute of Ultrasound in Medicine (AIUM), 1994
- European Medical Device Directive (93/42/EEC)

The BVI 6100 is a Track 1 System and meets the FDA's pre-amendment acoustic output limits for "fetal imaging and other" applications.

5) Intended Use:

The intended uses of the BVI 6100 System, as defined by FDA guidance documents, is for Abdominal (Adult and Pediatric) applications.

The BVI 6100 System is intended to project ultrasound energy through the lower abdomen of a nonpregnant patient to obtain an image of the bladder and measure urinary bladder volume non-invasively on an intermittent basis. The indications for use are the same as for Diagnostic Ultrasound's predicate devices. The BladderScan BVI 6100 is contraindicated for fetal use and for use on pregnant patients.

6) Technological Characteristics:

The BVI 6100 and its integrated 3.7 MHz mechanical sector transducer operate only in B-mode to locate and automatically measure bladder volume. Bladder volume, patient gender, non-optimal directional aiming, battery status, and usage rate indicators are all displayed on the BVI 6100 scanner. The ultrasonic power transmitted by the System is not user adjustable.

The hand-held BVI 6100 is applied to the patient's abdomen with a single patient use Sontac® hydrogel pad, manufactured by Diagnostic Ultrasound to optimize the performance of the BVI 6100. The transducer collects cross-sectional images of the bladder from twelve (12) scan planes. From this information, the BVI 6100 constructs a finite element model of the bladder and automatically computes the volume of urine via volumetric integration.

A Calibration Targeting System, consisting of a heli-coil shaped calibration target along with a specially designed container, allows the user to easily scan a known geometrically shaped target. Data may be optically transmitted to a remote location when connected to the clinician's personal computer via a communication cradle. Connection to this communication cradle allows for battery charging, remote calibration, usage monitoring, software updates, and data transfer through a web-based interface, referenced as "ScanPoint™". The BVI 6100 System also includes a universal charger cradle for the non-replaceable lithium ion battery incorporated into the handheld instrument.

Measurement Techniques-Section 4.2: Electrostatic Discharge/Immunity Test-Basic EMC Publication

IEC 61000-4-3:1997, International Electrotechnical Committee, Electromagnetic Compatibility (EMC)-Part 4. Testing and Measurement Techniques-Section 3: Radiated Radio-Frequency, Electromagnetic Field Immunity Test

IEC 61000-4-4:1995, International Electrotechnical Committee, Electromagnetic Compatibility (EMC)-Part 4. Testing and Measurement Techniques-Section 4, Electrical Fast Transient/Burst Immunity Test-Basic EMC Publication

IEC 61000-4-5:1999, International Electrotechnical Committee, Electromagnetic Compatibility (EMC)-Part 4. Testing and Measurement Techniques-Section 5, Surge Immunity Test

CISPR11:1997, International Electrotechnical Commission, International Special Committee on Radio Interference. Industrial, Scientific, and Medical (ISM) Radio-Frequency Equipment Electromagnetic Disturbance Characteristics-Limits and Methods of Measurement

IEC 60601-2-37:2001, International Electrotechnical Commission, Medical Electrical Equipment-Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment

Medical Ultrasound Safety, American Institute of Ultrasound in Medicine (AIUM), 1994

Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medicine, 1998.

Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment: A Standard for How Manufacturers Should Specify Acoustic Output Data, American Institute of Ultrasound in Medicine, 1998.

The BVI 6100 will be cleared and/or approved by the following agencies:

–U. S. Food and Drug Administration (FDA)

–Canadian Standards Association (CSA)

– European Medical Device Directive 93/42/EEC Notified Body

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2002

Diagnostic Ultrasound Corporation
% Mr. Mark Job
Program Manager
TÜV Product Service, Inc.
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K022153
Trade Name: BladderScan™ BVI 6100 Ultrasound 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 IYO and ITX
Dated: August 5, 2002
Received: August 6, 2002

Dear Mr. Job:

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 BladderScan™ BVI 6100 Ultrasound System, as described in your premarket notification:

Transducer Model Number

3.7 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)

K022153

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: BladderScan™ BVI 6100 Ultrasound System

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

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P						
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicles)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA (K955840, K915436)

Prescription Use (Per 21 CFR 801.109)

David G. Lynn

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022153

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