JAN 25 1999

510(k) Summary

BladderManager® Personal Care Instrument PCI 5000

Common/Classification Name: Ultrasonic Bladder Volume Instrument/ Pulsed Echo Ultrasonic Imaging System as classified under 21 CFR 892.1560

Diagnostic Ultrasound Corporation.
18109 NE 76th Street
Redmond, Washington 98052

Phone (206) 867-1348
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Contact: Gerald McMorrow, MSEE

Prepared: July 14, 1998

A. Legally Marketed Predicate Devices

The BladderManager PCI 5000 is substantially equivalent to Diagnostic Ultrasound Corporation's previous model BladderManager PCI 5000 (K955840).

B. Device Description

The BladderManager PCI 5000 is a portable, battery powered ultrasound instrument designed for a patient to non-invasively monitor his or her bladder volume on an intermittent basis.

C. Indications for Use

The BladderManager PCI 5000 projects ultrasound energy through the lower abdomen of the non-pregnant patient to obtain an image of the bladder that is used to determine bladder volume non-invasively.

D. Substantial Equivalence Summary

The predicate device also provides the same function and technological characteristics as described above for the new model BladderManager PCI 5000. The two models have the same indication for use and use the same mechanical sector scanning transducer to obtain the necessary data.

The new model is nearly identical to the predicate BladderManager PCI 5000 (K955840) with the following exceptions: the new model can be worn continually

by the patient with use of a garment, and can be set to automatically measure bladder volume at preset time intervals. Although there are some technological differences (software) incorporated to provide these features, the differences are minor and do not raise new questions of safety and effectiveness. In addition, accepted scientific methods exist for assessing the effects of the technological differences.

E. Technological Characteristics

The ultrasonic and electrical properties of the device are unchanged. The only modification is the addition of the autoscan mode, and the ability to wear the device with a garment. All safety testing reported in the previous model BladderManager PCI 5000 510(k) submission is applicable.

The hardware of the BladderManager PCI 5000 is unchanged. All testing reported in K955840 is applicable to this model.

A minor software change initiates the scan automatically at preset time intervals. Other than this change, the software for the current model is unchanged from the predicate model.

F. Testing

A clinical study was performed to assess the capability of the BladderManager PCI 5000 to automatically track the bladder filling and emptying in a supine adult, and to alarm at a specific bladder volume. In this study, bladder volume measured in autoscan mode was compared to volume measured in the manual mode, and to voided volume.

Forty subjects were enrolled at two sites. Subjects were trained in the use of the device and fitted with the garment. The instrument was set to scan every 15 minutes and the alarm was set to 250 cc.

When the alarm sounded, the autoscan volume was recorded. The instrument was then placed in manual mode and the bladder volume was measured manually and recorded. The subject was then asked to void into a graduated receptacle. The voided volume was measured, and the post void residual volume was then manually measured and recorded.

These data and analyses demonstrate that the BladderManager PCI 5000 used to measure bladder volume in autoscan mode is substantially equivalent to the BladderManager PCI 5000 used in manual mode. The study also showed that the device can accurately alarm at a preset volume to allow the patient or caregiver time to manage the urological needs of the patient.

G. Conclusions

Diagnostic Ultrasound Corporation has demonstrated through its comparison of performance with the predicate device that the BladderManager PCI 5000 is equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 1999

Gerald McMorrow
President and CEO
Diagnostic Ultrasound Corp.
18109 NE 76th St.
Redmond, WA 98052

Re: K982568
BladderManager™ PCI 5000 and
BladderManager™ PCI 5000+ with option of garment held probe and automatic monitoring
Regulatory class: II/21 CFR 892.1560 and 21 CFR 892.1570
Procode: 90 IYO and 90 ITX
Dated: November 12, 1998
Received: November 13, 1998

Dear Mr. McMorrow:

We have reviewed your Section 510(k) 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 BladderMananger™ PCI 5000 and the BladderManager™ PCI 5000+, as described in your premarket notification:

Transducer Model Number

2 MHz scanhead

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 Paul Gammell, Ph.D.at (301) 594-1212.

Sincerely yours,

for David G. Schultz

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K982568

Device Name: BLADDERMANAGER® PCI 5000
AND BLADDER MANAGER® PCI5000+

Indications For Use:

The BladderManager® PCI 5000(+) is intended to project ultrasound energy through the lower abdomen of the non-pregnant in order to obtain an image of the bladder that is used to determine bladder volume non-invasively. This capability is provided in 2 fundamental modes; 1) hand held probe, aimed by user to obtain reading and 2) Automatically monitor bladder volume via a garment-held probe on non-mobile, supine patient. Patients and/or caregivers are alerted visually and/or audibly when the bladder volume exceeds a pre-programmed threshold.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982568

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

K982568

BLADDER MANAGER® PCI 5000

AND BLADDER MANAGER® PCI 5000 +

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each 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		X								
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

510(k) Number K982568