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510(k) SUMMARY

Diagnostic Ultrasound Corporation's
BladderManager™ Personal Care Instrument PCI 5000
BladderScan™ Bladder Volume Instrument BVI 5000

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared:	December 21, 1995

Name of Devices and Name/Address of Sponsor:

BladderManager™ Personal Care Instrument PCI 5000 (PCI 5000)
BladderScan™ Bladder Volume Instrument BVI 5000 (BVI 5000)

Diagnostic Ultrasound Corporation
18109 NE 76th Street
Redmond, WA 98052

Common or Usual Name

Ultrasonic Bladder Volume Instrument

Classification Name

System, Imaging, Pulsed Echo, Ultrasonic

Predicate Device

Diagnostic Ultrasound Corporation's BladderScan™ BVI 2500 (K 915436)

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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. The BladderScan BVI 5000 is similar, except that it is designed for use by the clinician with the added feature of a "docking cradle" containing an onboard computer that provides a hard copy printout of the scan images and the bladder volume.

Intended Use

The BladderManager PCI 5000 and BladderScan BVI 5000 **"project 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."**

This statement of intended use is identical to that of the predicate device.

Technological Characteristics Comparison

The BladderManager PCI 5000 and BladderScan BVI 5000 are substantially equivalent to the other currently marketed BladderScan BVI 2500 which is referenced above. The BladderManager PCI 5000 and BladderScan BVI 5000 and their predicate device are all pulsed echo ultrasonic imaging instruments dedicated to non-invasive measurement of urinary bladder volume. Although there are some technological differences between the BladderManager and its predicate, these differences are minor and raise no new questions of safety and effectiveness. In addition, accepted scientific methods exist for assessing the effects of the technological differences. The BladderManager PCI 5000 and BladderScan BVI 5000 differ from the BladderScan BVI 2500 in scanhead shape, patient contact materials, scan angle, ultrasonic coupling material, lateral resolution, acoustic output, and transducer model number. However, accepted scientific methods for biocompatibility testing, ultrasonic acoustic output testing, and clinical testing demonstrated that the subject devices are substantially equivalent to the predicate device in terms of safety. Also, accepted scientific methods for clinical accuracy testing demonstrated that the subject devices are substantially equivalent to the predicate device in terms of effectiveness.

Performance Data

Non-clinical testing included acoustic output testing, thermal, mechanical, and electrical safety testing, electromagnetic emissions and immunity testing, and biocompatibility testing. All non-clinical testing demonstrated that the subject devices are substantially equivalent to the predicate device in terms of safety, effectiveness, and performance.

Preliminary clinical testing of the BladderManager PCI 5000 and the BladderScan BVI 5000 was performed on adult ambulatory volunteers. No significant adverse effects or complications were noted. The results demonstrated that the device is substantially equivalent to the predicate device in terms of safety and effectiveness.

Clinical testing of the BladderManager PCI 5000 was performed at three independent clinical sites using adult spinal cord diseased patients, as well as healthy volunteers. No significant adverse effects or complications were noted. The results demonstrated that the device is substantially equivalent to the predicate device in terms of safety and effectiveness.

Conclusion

Non-clinical and clinical testing methods demonstrate that the device is safe and effective, and performs as well as the legally marketed predicate device.