Diagnostic Ultrasound Corporation
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USA

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510(k) SUMMARY

Diagnostic Ultrasound Corporation Gel Pad (DxU Gel Pad)
Accessory for Use With the
BladderScan™ Bladder Volume Instrument BVI 5000 (K955840)
BladderManager™ Personal Care Instrument PCI 5000 (K955942)

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: September 6, 1996

Name of Device and Name/Address of Sponsor:

Diagnostic Ultrasound Gel Pad, for use with the
BladderScan™ Bladder Volume Instrument BVI 5000 (K955840)
BladderManager™ Personal Care Instrument PCI 5000 (K955942)

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Common or Usual Name

Ultrasonic Bladder Volume Instrument

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Classification Name

System, Imaging, Pulsed Echo, Ultrasonic

Predicate Device

Koolgel wound dressing (K881731), for use with the
BladderScan™ Bladder Volume Instrument BVI 5000 (K955840)
BladderManager™ Personal Care Instrument PCI 5000 (K955942)

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. For both instruments, the scanhead is applied to the patient's abdomen with a hydrogel pad providing ultrasound transmission coupling between the scanhead and the patient's body. Standard ultrasound gel can also be used by itself or in addition to the hydrogel pad, depending on patient preference. The hydrogel pad used in the original 510(k) submission, the Koolgel gel pad, is composed of water and polyethylene oxide, manufactured with the identical formulation as a previously cleared device (Ad-Heal wound dressing, K881731). The **object of this submission**, the **DxU Gel Pad**, is composed of distilled water, glycerol, gracillaria agar, carrageenan, methyl paraben, and propyl paraben.

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 unchanged with the DxU Gel Pad.

Technological Characteristics Comparison

The DxU Gel Pad accessory to the BladderManager PCI 5000 and BladderScan BVI 5000 is substantially equivalent to the Koolgel gel pad used in the original 510(k) submission for these two devices. The DxU Gel Pad and its predicate gel pad are both semisolid compounds

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designed to provide ultrasonic coupling between the instruments' ultrasound transducer and the skin of the patient. The instruments themselves are pulsed echo ultrasonic imaging instruments dedicated to non-invasive measurement of urinary bladder volume. Although there are some technological differences between the DxU Gel Pad and its predicate accessory, 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 DxU Gel Pad differs from the Koolgel gel pad in composition of materials, however, accepted scientific methods for biocompatibility testing and clinical performance testing demonstrated that the subject device accessory is substantially equivalent to the predicate device accessory in terms of safety. Also, accepted scientific methods for bench testing and clinical performance testing demonstrated that the subject device accessory is substantially equivalent to the predicate device accessory in terms of effectiveness.

Performance Data

Non-clinical testing included density, speed of sound, and acoustic impedance measurements, and biocompatibility testing. All non-clinical testing demonstrated that the subject device accessory is substantially equivalent to the predicate device accessory in terms of safety, effectiveness, and performance.

Clinical testing of the DxU gel pad with the BVI/PCI 5000 was performed on healthy volunteers, as well as actual spinal cord injured subjects familiar with the instrument. No significant adverse effects or complications were noted. The results demonstrate that the device accessory is substantially equivalent to the predicate gel pad in terms of safety and effectiveness.

Conclusion

Non-clinical and clinical testing methods demonstrate that the device accessory is as safe, as effective, and performs as well as the legally marketed predicate device accessory. The DxU Gel Pad is substantially equivalent to the Koolgel gel pad with respect to intended use, technological characteristics, and clinical performance.