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ProUroCare Medical Announces Filing of Request to Classify the Prostate Mechanical Imager (“PMI”) as a Class II Device

MINNEAPOLIS, Minn. (May 24, 2010) – ProUroCare Medical, Inc. (OTCBB: PUMD, PUMDU and PUMDW), a provider of proprietary imaging products, today announced that a meeting was held with the FDA on May 19th to review the 510(k) application for the Prostate Mechanical Imaging (PMI) system, also known as the ProUroScanTM system, and to discuss the requirements for filing a reclassification request (a de novo filing) in accordance with Section 513(f)(2) of the Federal Food, Drug and Cosmetic Act. On May 21st, a de novo application was filed with the FDA for the ProUroScan (PMI) system.

Following the filing of the initial 510(k) application for the PMI system, the FDA issued a letter stating that the PMI system was not “substantially equivalent” to currently marketed devices. As required by the Section 513(f)(2) guidance document, a submission was made on May 19th to request 510(k) clearance under the de novo process. This request asked the FDA to define mechanical imaging systems as devices that are intended to produce an elasticity image of the prostate as an aid in documenting abnormalities of the prostate that are initially identified by digital rectal examination and to be used by physicians as a documentation tool.

The de novo submission also recommended that the classification regulation state that a “mechanical imaging system” device consists of a trans-rectal probe with pressure sensor arrays and a motion tracking system that provides real time images of the prostate. These proprietary components are unique to the ProUroScan system.

The primary benefit of a de novo filing is that it will allow the agency to review and potentially classify mechanical imaging devices, like the ProUroScan, as a Class II device subject to special controls. Once cleared, the PMI may serve as a predicate for future filings and expanded indications for use. The time allowed for review of the de novo application is defined by statute under Section 513(f)(2).

“The FDA meeting was very productive and the agency indicated a willingness to work with us on the review of the de novo filing,” said Rick Carlson, CEO of ProUroCare.

About ProUroCare Medical, Inc.

ProUroCare Medical, Inc. is a publicly traded company engaged in the business of creating innovative medical imaging products. The company's current focus is the ProUroScan prostate imaging system, which is used to map abnormalities of the prostate detected by DRE. Based in Minneapolis, Minn., ProUroCare is traded on the OTCBB.

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Safe Harbor Statement

This news release contains certain "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are typically preceded by words such as "believes," "expects," "anticipates," "intends," "will," "may," "should," or similar expressions. These forward-looking statements are not guarantees of ProUroCare's future performance and involve a number of risks and uncertainties that may cause actual results to differ materially from the results discussed in these statements. Factors that might cause ProUroCare's results to differ materially from those expressed or implied by such forward-looking statements include, but are not limited to, the ability of ProUroCare to find adequate financing to complete the development of its products; the high level of secured and unsecured debt incurred by ProUroCare; the dependence by ProUroCare on third parties for the development and manufacture of its products; and other risks and uncertainties detailed from time to time in ProUroCare's filings with the Securities and Exchange Commission including its most recently filed Form 10-K and Form 10-Q. ProUroCare undertakes no duty to update any of these forward-looking statements.