**ProUroCare Medical Submits Cleaning and Disinfection Protocol to FDA**

**For Review Prior to Submission of 510k**

**MINNEAPOLIS–** ProUroCare Medical Inc. (PUMD), provider of proprietary medical imaging products, has submitted a Cleaning and Disinfection Protocol for its ProUroScan™ prostate mechanical imaging system to the U.S. Food & Drug Administration (FDA). The submission requests that the FDA review the cleaning and disinfection validation protocol for the ProUroScan's sensor probe prior to initiating testing and preparation of a final test report. The results of this study will be incorporated in the multi-use labeling claim that the company will pursue in a subsequent 501(k) filing.

On May 1, 2012, the company announced it had received clearance from the FDA to commercialize the ProUroScan system as a single use device. The approval paves the way for men and their families to receive high-resolution visual documentations as an aid in detecting prostate abnormalities that were previously detected by digital rectal examination (DRE). At that time, the company indicated it would be submitting a subsequent 510k that incorporated cleaning and disinfection instructions for the ProUroScan probe to support a change from a single use device to a reusable labeling indication. A key step in ensuring timeliness of FDA's marketing clearance of this subsequent 510k is obtaining FDA's agreement that the company's cleaning and disinfection testing protocol meets FDA's guidelines.

"It is important to note that we have discussed this process with the FDA and this submission provides a means to receive agency feedback on our validation protocol". said Larry Getlin, a director of the company. Following FDA's agreement on the content of the cleaning and disinfection process, the company plans to complete the necessary supporting testing of the ProUroScan probe and then file a 510k for an indication as a reusable device.

The prostate imaging system's FDA 510(k) was first submitted by ProUroCare's development partner Artann Laboratories, Inc. and later processed in accordance with the *de novo* provisions accounted for in Section 513(f)(2) of the Federal Food, Drug and Cosmetic Act. The FDA filings were supported by data from a 2009 National Institute of Health and National Cancer Institute-supported clinical study of patients evaluated at five leading U.S. medical centers, as well as an earlier study conducted specifically at the Robert Wood Johnson Medical Center in New Brunswick, N.J.

**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 ProUroScan system, an elasticity imaging technology used to document abnormalities of the prostate previously detected by a digital rectal examination, received commercial clearance from the FDA on April 27, 2012. Based in Minneapolis, the company's stock trades on the OTCQB market (www.otcmarkets.com).

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*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 impact and timing of actions taken by the FDA and other regulatory agencies with respect to ProUroCare's products and business; 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.*

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