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FOR IMMEDIATE RELEASE

PCI Medical Announces 510(k) Submission to FDA for Automated Reprocessors for Endovaginal/Endorectal Probes and TEE Probes

PCI Medical announces that it has submitted the GUS ASTRA VR™ and GUS ASTRA TEE™ to the U.S. Food and Drug Administration (FDA) for 510(k) clearance, and that the submission is now in substantive review.

The GUS ASTRA VR is an automated reprocessor for the high-level disinfection of endovaginal/endorectal ultrasound probes. The GUS ASTRA TEE is an automated reprocessor for the high-level disinfection of transesophageal (TEE) probes.

Both systems will feature the ability to disinfect one or two probes at a time while allowing you to use a choice of high-level disinfectants. They will also minimize cycle costs by performing up to 250 cycles with a single gallon of disinfectant. A built-in barcode reader records and stores information including: type of disinfectant, probe and operator ID, temperature, date, time, and MRC pass or fail. This information is retrievable via a USB port.

“PCI Medical has been the leader in high-level disinfection of ultrasound probes for 20 years. This submission is in response to our customers’ desire to move away from expensive proprietary disinfectants and their need for automated capture and retrieval of data for compliance purposes,” Joe Turgeon, President of PCI Medical said. “The GUS ASTRA VR and GUS ASTRA TEE automated reprocessors would be exciting additions to our extensive product line.”

About PCI Medical The Experts in High-Level Disinfection®

For 20 years, PCI Medical has developed and manufactured high-level disinfection systems: GUS Disinfection Soak Stations™ used in over 6,000 facilities.

PCI Medical also manufactures GUS Storage Systems for endovaginal/endorectal, general purpose probes and TEE probes, spill kits, neutralizers and other accessories for high-level disinfection.

In addition to our quality products, the PCI Medical Disinfection Team helps facilities to become or stay compliant in the high-level disinfection process, from pre-cleaning to storage. We are **The Experts in High-Level Disinfection**.

For more information about PCI Medical products and educational offerings, please visit www.pcimedical.com