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FDA Provides Clearance of TYRX Antibacterial Patch for Soft Tissue Repair

Monmouth Junction, NJ, (April 27, 2010) -- TYRX, Inc. announced that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance to market AIGIS_{RX}[®] ST, its antibacterial product for the surgical repair of damaged or ruptured soft tissue.

TYRX had previously received 510(k) clearance to market a product for hernia repair and other abdominal soft tissue deficiencies. The new clearance adds the use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue. AIGIS_{RX} ST delivers the antimicrobial agents, rifampin and minocycline. These antimicrobial agents have been shown to reduce infections associated with medical devices in multiple randomized controlled trials.

“AIGIS_{RX} ST offers physicians a new tool to help address the relatively high rate of infection associated with a variety of soft tissue procedures”, remarked Rabih Darouiche, M.D., Director, Center for Prostheses Infection, Baylor College of Medicine. “Major infection rates of 3% to 4% are common and there is no accepted, locally acting means to help prevent these infections.”

AIGIS_{RX} ST extends the proprietary antibacterial technology developed by TYRX to gastrointestinal surgeons and general surgeons. AIGIS_{RX} ST has a resorbable polymer containing the antimicrobial agents rifampin and minocycline to help provide protection from microbial colonization. TYRX currently markets AIGIS_{RX} Envelope and AIGIS_{RX} FS which incorporate the same antibacterial technology and are cleared for use with the implantation of pacemakers and cardiac defibrillators. AIGIS_{RX} devices have been successfully implanted in over 9,000 patients in the United States.

“We were pleased that the FDA cleared this important new application.” said Robert White, TYRX CEO. “This is our first FDA cleared product outside of the cardiac rhythm management and hernia repair markets and we are now considering various commercialization strategies.”

About TYRX, Inc.

TYRX, Inc. commercializes innovative, implantable combination drug/device products focused on infection control including the AIGIS_{Rx}[®] Antibacterial Envelope and the recently released AIGIS_{Rx}[®] FS. AIGIS_{Rx} products contain antimicrobial agents, rifampin and minocycline, which have been shown to reduce infection by organisms representing a majority of the infections reported in cardiac rhythm device (CRDM) related endocarditis, including "superbugs" or MRSA*.

Following commercial release in 2008, the AIGIS_{Rx} Envelope has been implanted in over 9,000 patients nationwide. The company estimates that approximately 2% of all U.S. CRMD patients in 2010 will receive an AIGIS_{Rx} product during their procedure.

TYRX, Inc. is an ISO 13485:2003 certified medical device manufacturer and its products utilize technology licensed exclusively from Rutgers, Baylor College of Medicine, and The University of Texas M. D. Anderson Cancer Center.

* Based upon preclinical *in vitro* and *in vivo* data. Data on file at TYRX and published in PACE 2009; 32(7) 898-907

For more information, please visit www.TYRX.com.