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TYBER MEDICAL ANNOUNCES FDA 510(k) CLEARANCE OF BIOTY™, A MODIFIED SURFACE TREATMENT

Morristown, New Jersey, March 1st, 2016 – Tyber Medical, LLC, a privately held medical device company focused on developing innovative orthopedic and spine devices for private label opportunities, announces FDA clearance of [BioTy™, a Modified Surface Treatment](#) for use on their Headless Screw System. In addition, Tyber Medical has expanded their Exclusive Licensing Agreement with Northeastern University to further enhance the BioTy™ proprietary technology and intellectual property.

This initial FDA clearance is the first step in a series of regulatory submissions that are expected to enable the company to add BioTy™ to current and future products in the Tyber Medical product portfolio. In addition to Tyber Medical products, the company is currently exploring BioTy™ commercialization strategies with potential partners. The BioTy™ surface treatment is a nano-scale technology that features a unique proprietary process protected by multiple issued and pending patents. The technology modifies the surface characteristics of medical devices for advanced indications yet to be disclosed, but under development through the FDA review process.

Tyber Medical, in collaboration with Northeastern University, is [conducting multiple studies](#) on BioTy™ to analyze cellular response with this technology. The company expects these results to support claims of a statistically significant decrease in bacterial adherence as compared to

non-surface modified implants. “Based on initial results, we expect this technology to set the new market standard for orthopedic implants and will be applicable across the entire market” says Rui Ferreira, Vice President of R&D at Tyber Medical. “We believe this partnership and technology demonstrates that Tyber Medical and Northeastern University are committed to not only developing orthopedic implants, but also scientific backed technologies that combine bioengineered surfaces and structural implants.”

“With the excellent reputation of Northeastern University as a research institute, as well as Tyber Medical’s expertise in rapid device development and surface modification, the BioTy™ modified surface treatment technology and exclusive licensing agreement go hand in hand with Tyber Medical’s business model of providing rapid access to portfolio enhancing technologies” says Jeff Tyber, CEO and President of Tyber Medical.

The FDA clearance, as well as the exclusive licensing agreement, are expected to continue to add game changing technology to the already unique products of Tyber Medical’s comprehensive portfolio of CE Marked and FDA approved private labeled implants. Tyber Medical’s portfolio now includes over 46,000 different product configurations within 22 different product lines, including the first available Modified Surface Treatment Technology. All of these technologies are available through Tyber Medical private label partnerships.

About Tyber Medical:

Tyber Medical, LLC, Morristown, New Jersey, a private labeler Original Equipment Manufacturer (OEM), is creating new pathways to [regulatory approved implants and instruments](#) for [orthopedic companies, large distributors, and hospital organizations](#). Tyber Medical designs and develops full class II orthopedic systems, verifies and validates those systems using a QSR and ISO 13485 certified quality system, and pursues and maintains both US (FDA 510k) and OUS (CE Mark) regulatory approvals. Current products include the opening osteotomy system, headless compression screws, cervical plating system, lateral retractor system, and spinal interbody spacers featuring both standard sterile and non-sterile PEEK and [TyPEEK®](#), a proprietary titanium plasma sprayed PEEK. For more information, please visit www.tybermedical.com.

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