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OSSIO receives FDA 510(k) clearance for OSSIOfiber Bone Pin Product Family

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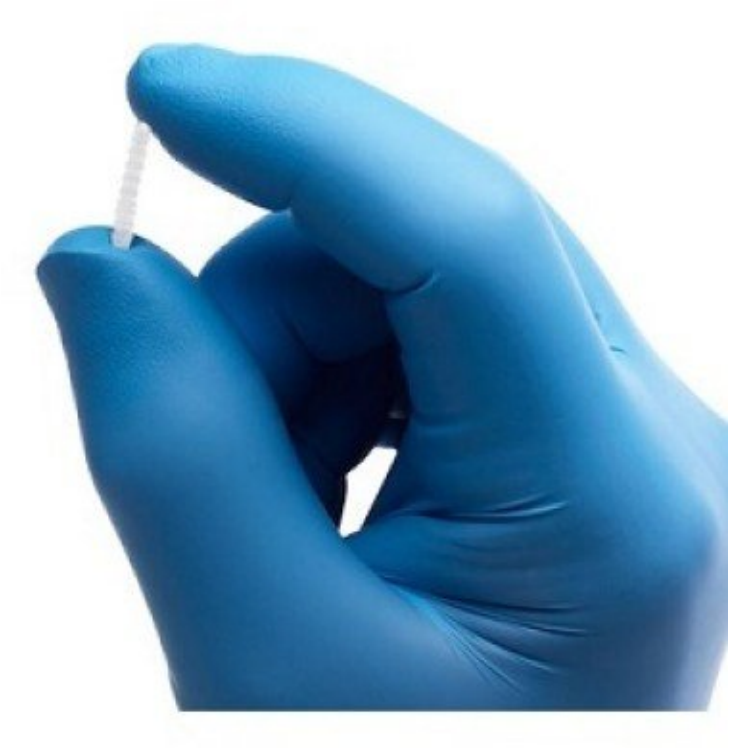

OSSIO, an orthopedic fixation company has announced that its OSSIOfiber Bone Pin Family has received 510(k) market clearance from the U.S. Food and Drug Administration (FDA).

This technology features a proprietary bio-integrative material to provide stability and secure bone fixation during the healing process, leaving no permanent hardware behind. While the OSSIOfiber platform will have broad application across the spectrum of orthopedics, its first commercial use will be in the foot and ankle segment for the treatment of forefoot conditions where hardware removal surgeries are prevalent.

The OSSIOfiber Bone Pin Family comprises the company's OSSIOfiber Intelligent Bone Regeneration Technology, a new category of non-permanent fixation material that aims to be the first credible replacement to permanent fixation implants. Made from a proprietary natural mineral fiber matrix, its bio-integrative material properties provide surgeons with a more biologically friendly way to restore patient stability and mobility while leaving nothing permanent behind.

At the time of surgery, OSSIOfiber provides ease of insertion and secure fixation without requiring any changes to surgeons' existing techniques. Initially, the mechanical strength of the novel implant is significantly higher than cortical bone, and its performance supports bone regeneration throughout the healing process. It then gradually transfers load to the native bone

following the critical rehabilitation phase. Unlike metal, the stiffness of OSSIOfiber is a better mechanical match to bone and this improved bone compliance can prevent stress risers and weakening of the bone around the implant. As confirmed in pre-clinical studies, full integration into the surrounding anatomy takes place within approximately 18-24 months, leaving only native bone behind with no residual hardware.

Metal implants represent the current standard of care in orthopedic fixation; however, permanent hardware creates a sub-optimal healing environment, which can lead to patient dissatisfaction and increasing healthcare costs due to post-operative complications and secondary removal surgeries. Over the course of the last few decades, there have been numerous attempts to develop fixation implants from various bio-resorbable materials, but these devices have fallen short in providing the required mechanical strength or optimal degradation profiles to avoid burst releases of acidic by-products and local inflammation.

Brian Verrier, CEO, OSSIO said, “Today’s FDA clearance of the OSSIOfiber Bone Pin Family marks a significant milestone for our company, as we bring a new category of orthopedic fixation to the U.S. market. We look forward to partnering with surgeons throughout the United States to integrate the OSSIOfiber platform into their surgical treatment options, ultimately changing the current standard-of-care in orthopedic fixation by encouraging natural bone healing that avoids unnecessary hardware removal surgeries and improves the overall healthcare economics of orthopedics. This regulatory achievement supports our overall mission to transform the patient experience.”

OSSIO expects to commercially launch the OSSIOfiber Bone Pin Family in the United States in the second quarter of 2019.

Additionally, a European multi-center clinical trial is currently underway assessing the safety and performance of the OSSIOfiber Hammertoe Fixation Implant, with the first patient treated last month by Dr. Luke Cicchinelli at Clínica Guillén in Vigo, Spain. The trial results will serve to support the company’s Conformité Européene (CE) Mark application for approval of the OSSIOfiber Hammertoe Fixation Implant in 2020.

The proprietary OSSIOfiber technology can address many surgical applications through manufacturing of endless implant designs, including pins, screws and plates. The company intends to pursue multiple applications in the distal extremity, trauma, sports, reconstruction, pediatrics, and spine segments.