

4WEB Medical Announces FDA 510(k) Clearance of its Cervical Stand-Alone Interbody Fusion Device

Company expands implant portfolio with the addition of the Cervical Spine Truss System - Stand-Alone

DALLAS, Aug. 28, 2019 /PRNewswire/ -- 4WEB Medical, an orthopedic device company focused on developing innovative implants utilizing its proprietary Truss Implant Technology™, announced today that the company has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its Cervical Spine Truss System-Stand Alone (CSTS-SA) Interbody Fusion Device.

Consistent with 4WEB's existing product portfolio, CSTS-SA has an open architecture, Advanced Structural Design that incorporates the company's proprietary Truss Implant Technology™. The CSTS-SA product is designed to allow fixation screws to be placed through the truss implant and into the adjacent vertebral bodies creating a zero-profile stand-alone construct that removes the need for traditional plate and screw fixation. Additionally, the device features a single-step locking mechanism that provides surgeon users confidence in the performance of the stand-alone construct. The Cervical Stand-Alone product line will be available in multiple footprints, lordotic angles, heights and will be delivered in sterile packaging for hospital efficiency and patient safety. 4WEB expects to take the product to market at the beginning of the fourth quarter.

"We are thrilled to be able to expand our market leading portfolio in the titanium interbody space. The addition of the Cervical Spine Truss System-Stand Alone product line not only broadens our current portfolio, but represents the first of many products to be released that will provide significant growth for the organization," said Jim Bruty, Sr. Vice President of Sales and Marketing. "4WEB will continue to provide clinicians with disruptive, clinically beneficial technology achieved through product development."

4WEB Medical's proprietary Truss Implant Technology™ utilizes the concept of mechanobiology to simulate cellular activity at the surgical site. The manufacturing process used to produce the implant's Advanced Structural Design creates a hierarchical surface roughness with features that span from the macro to nano scale. In-vitro testing has shown that stem cells attached to 4WEB's titanium implant surface exhibited increased gene expression of certain osteogenic markers when compared to smooth titanium and PEEK.

The company remains focused on accelerating growth over the next 5 years with investments in product development, procedural based solutions and clinical research.

About 4WEB Medical

4WEB Medical is an orthopedic implant device company founded in 2008 in Dallas, Texas. Thirty years of research in topological dimension theory led to the discovery of a novel geometry, the 4WEB, that can be used as a building block to create high-strength, lightweight web structures. The company leveraged this breakthrough along with cutting-edge 3D printing technology to develop 4WEB Medical's proprietary truss implant platform. The 4WEB Medical product portfolio includes Cervical, Anterior, Posterior and Lateral Spine Truss Systems, as well as the Osteotomy Truss System and custom implant services for extremity, tumor and trauma procedures. To learn more about 4WEB Medical's Truss Implant Technology™ visit www.4webmedical.com.

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