Penderia Technologies Secures FDA Breakthrough Device Designation for Sensorized Soft Tissue Anchor System

The medical device startup also was approved for TAP enrollment from the FDA, speeding the development of its wireless sensor platform.

EUGENE, OR, UNITED STATES, February 28, 2025 /EINPresswire.com/ -- Penderia Technologies, a company developing wireless sensor technologies for orthopedic applications and in collaboration with MRC Global, LLC, recently received the FDA's Breakthrough Device Designation for its Sensorized Soft Tissue Anchor System. Additionally, the system was accepted into the FDA's Total Product Life Cycle Advisory Program (TAP), a limited enrollment program meant to enhance market pathway collaboration for breakthrough technologies. Soft tissue anchors target procedures such as ACL reconstruction, rotator cuff repair, and ankle syndesmosis repair.

"Penderia's implantable sensor addresses a critical gap in orthopedic soft tissue repair, where insufficient technology limits clinicians' ability to understand and apply data on fixation tension to improve surgical precision and patient outcomes," said Penderia inventor, co-founder, and CTO Dr. Keat Ghee Ong.

Penderia's device utilizes an anchor, compatible with current surgical techniques, that is embedded with proprietary wireless sensing technology to measure tension remotely throughout the entire range of joint motion during and after surgery. This direct feedback does not exist elsewhere and has the potential to improve success both at the time of surgery and during recovery.

With the Breakthrough Device Designation and TAP enrollment, Penderia will benefit from early, frequent, and strategic engagement with the FDA, reimbursement experts, specialty societies and patient organizations, along with priority review for future regulatory submissions. These programs are reserved for novel medical devices that enhance the standard of care for irreversibly debilitating conditions, with a primary goal of expediting patient access to such devices by providing support throughout the development process. This support will expedite

the development, evaluation, and commercialization of Penderia's Sensorized Soft Tissue Anchor System.

"Penderia believes our platform will improve the standard of care in soft-tissue repairs and are excited to receive the Breakthrough Device designation as validation of our vision," said Penderia CEO Stephen Laffoon. "We look forward to engaging with the FDA through the TAP program as an important milestone on the way to clinical impact."

About Penderia Technologies, Inc.:

Penderia Technologies, Inc is a privately held medical device startup founded in 2020 to commercialize technology from the Phil and Penny Knight Campus for Accelerating Scientific Impact at the University of Oregon. The company is developing innovative wireless sensors for intra- and post-operative monitoring of critical load measurements along implanted hardware to enhance surgical precision and improve patient outcomes. Penderia has successfully demonstrated feasibility of its technology in cadaver and benchtop studies with funding from the National Institute of Health, Business Oregon, Launch Oregon, and private investors. Penderia is headquartered in Eugene, Oregon at the Papé Family Innovation Center.

The Sensorized Soft Tissue Anchor System is not available commercially at this time.

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