

FOR IMMEDIATE RELEASE

ALLUMIN8™ Receives FDA 510(k) Clearance for A8 INTEGR8™ Pedicle Screw System

First 3D-printed pedicle screw cleared in 5.5mm diameter, expanding options for surgeons and patients.

St. Louis, MO - October 21, 2025 - ALLUMIN8™, recognized by Orthopedics This Week as 2024 “Best Technology in Spine” for advancing innovation in spine care, today announced the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for the company’s A8 INTEGR8™ Porous Pedicle Screw System, offering the first 5.5mm diameter pedicle screw produced through additive manufacturing.

This clearance establishes a new benchmark in the design and mechanical performance of 3D-printed spinal fixation systems, underscoring ALLUMIN8™’s commitment to advancing safe, effective, and reliable solutions for surgeons and patients.

Purpose-Driven Innovation

The A8 INTEGR8™ Pedicle Screw was conceived from firsthand experiences with the challenges of failed spinal fusion surgeries. These personal insights inspired a six-year development effort to engineer a device capable of meeting the most demanding mechanical testing standards with a vision of improving long-term construct stability to reduce the global reoperation rate of spine fusions.

Defining a New Frontier in Spine Care

The A8 INTEGR8™ System represents the foundation of a broader vision ALLUMIN8™ calls Therapeutic Hardware™ - a platform of next-generation orthopedic and spine implants designed to integrate advanced surface architecture and precision engineering with therapeutic delivery to treat nearly 300 disease states with bone contributing to spinal fusion failures.

The company’s approach leverages additive manufacturing to enable Gaussian topography features designed to support osseointegration and future compatibility with localized biologic delivery concepts under research.

Key Engineering Features

- Cultiv8 Lattice: Proprietary Gaussian lattice topography, designed by CTO Matthew Shomper, reflective of the unique pattern of vertebral bone, and is designed to promote mechanical interlock and surface area for bone integration. The topography is integrated throughout the length of the screw shank.
 - A8 Circul8™ Adapter (not FDA cleared for sale in the US): Optional modular interface enabling intraoperative access for surgeon-directed injections, bone marrow draw, and/or cell delivery.
 - Screw Thread In-growth: a patent-pending design feature with topography on the actual screw threads for purchase and ingrowth within pedicle bone.
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Validated Through Rigorous Testing

ALLUMIN8™ performed extensive mechanical evaluations in accordance with ASTM F1717, F1798, F543, and F2193 to assess the static and fatigue strength, torsional resistance, and connection integrity.

Results demonstrated high durability and resistance to fatigue at critical transition zones (an area of common failure among conventional screw designs). These findings contributed to the FDA's determination of substantial equivalence.

Addressing a Widespread Need

Spinal fusion procedures remain among the most frequently performed surgeries worldwide, with revision rates driven by complex mechanical and biological factors. By focusing on design integrity and data-driven validation, ALLUMIN8™ aims to reduce the mechanical complications contributing to reoperations, supporting improved surgical confidence and long-term outcomes.

International distribution plans are already underway in the US, India, Dubai, Australia, Taiwan, and Japan.

Leadership Perspective

“This clearance marks a pivotal milestone for our team and the dawn of a new era uniting spine technology with therapeutic innovation,” said Alyssa Huffman, Founder & CEO of ALLUMIN8™. “It embodies the power of persistence and purpose; merging advanced engineering with a deep

understanding of bone biology, biomechanical failure, and the real-world needs of patients and surgeons. We're proud to begin shaping the next evolution of spinal fixation where hardware not only supports, but heals."

About ALLUMIN8™

ALLUMIN8™ is a U.S.-based medical technology company pioneering Therapeutic Hardware™ - a new class of spine and orthopedic implants engineered through additive manufacturing to integrate mechanical performance with biologic potential. By merging data-driven design, rigorous testing, and multidisciplinary collaboration, the company seeks to improve outcomes and redefine the standards of care for complex spinal pathology.

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