

SDIP Innovations Gains 510(k) for JAZBI™ Resorbable Bone Void Filler

SDIP Innovations was granted FDA 510(k) clearance to market the JAZBI™ Bone Void Filler, designed to support bone regeneration and healing. The U.S. clearance follows nearly a decade of research, development, and manufacturing investment by the Australian biomaterials company. This marks the company's entry into the U.S. bone graft substitute market and represents the first clearance of a device based on its proprietary JAZBI™ biomaterial.

JAZBI™ represents a novel biomaterial designed to resorb over time and be replaced by bone during the natural healing process. According to the company, the underlying JAZBI™ biomaterial has been engineered to enable the tailoring of its physical, mechanical, and biological characteristics to different clinical requirements, creating a foundation for a broader portfolio of regenerative products. The clearance represents the first commercial application of JAZBI™, with potential future applications across orthopaedics, spine, craniofacial surgery, dental surgery, and soft-tissue reconstruction.

A distinguishing feature of SDIP's strategy has been its investment in local manufacturing. The company has established comprehensive in-house manufacturing capabilities.

“JAZBI™ combines two primary components: an osteoconductive biphasic ceramic and our patented non-inflammatory polymer component, bringing them together in a composite structure with an optimised resorption rate and biological characteristics,” said Dr. Iman Manavitehrani, Chief Technology Officer and Co-founder. “We are scientifically and clinically investigating applications of the JAZBI™ platform across orthopaedics, spine, dental and craniofacial surgery, as well as next-generation biomaterial-based drug delivery systems,” he added.

Dr Maryam Parviz, Chief Executive Officer and Co-founder of SDIP Innovations, commented, “This FDA clearance is a major milestone for SDIP and an important validation of the proprietary JAZBI™ technology platform. It represents the first commercial application of a technology that has the potential to support multiple future products across a range of healthcare sectors.

“Our mission is to enable surgeons to innovate during surgery based on their patients' unique needs, and the future vision for JAZBI™ is centred on supporting that goal.”

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