Carlsmed Announces FDA Clearance for aprevo® Cervical Breakthrough Fusion Device

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CARLSBAD, Calif.--(BUSINESS WIRE)--Carlsmed, Inc. (“Carlsmed” or the “Company”) a MedTech company pioneering AI-enabled personalized spine surgery, today announced FDA 510(k) clearance for the aprevo® Cervical ACDF Interbody System. This milestone underscores Carlsmed’s commitment to advancing patient-specific spine surgery solutions that enhance outcomes and surgical precision.

The FDA previously granted Breakthrough Device designation for Carlsmed’s aprevo ® technology for the treatment of patients with cervical spine disease, recognizing aprevo’s potential to address unmet clinical needs and deliver superior patient care. The Company’s current portfolio of aprevo ® interbody fusion devices for the treatment of lumbar spine disease is commercially available in the U.S.

“This 510(k) clearance is a major step forward in our mission to make personalized spine surgery the standard of care,” said Mike Cordonnier, Chairman and CEO of Carlsmed. “More than 350,000 cervical fusion surgeries are performed annually in the U.S. The aprevo® Cervical ACDF Interbody System will set a new benchmark for improving outcomes for these patients.”

Designed to match the unique anatomical and procedural needs of each patient, personalized interbody devices have demonstrated significant improvements in patient outcomes compared to traditional fusion methods, as highlighted in recent clinical publications. The aprevo® devices are designed using Carlsmed’s proprietary technology platform that leverages AI-driven surgical planning software and digital production to create the personalized spine fusion devices that can be delivered in under two weeks.

“Personalized interbody devices like aprevo ® provide surgeons with tools designed to address each patient’s unique anatomy,” said Joseph Osorio, MD, PhD, and neurosurgeon at UC San Diego. “Having this technology available for cervical fusions marks a significant advancement in spinal surgery, with the potential to transform procedures by replacing the limitations of one-size-fits-all implants with level-specific customization, offering enhanced surface coverage and precise alignment, both of which are critical for improving patient outcomes.”

Carlsmed plans to commercially launch the aprevo® Cervical ACDF Interbody System in the U.S. in 2025, expanding its innovative product portfolio to further solidify its leadership in the personalized spine surgery market.

About Carlsmed

Carlsmed is a high-growth medical technology leader and pioneer in the personalized spine surgery market. Carlsmed’s mission is to revolutionize the standard of care in spine surgery by providing cutting-edge solutions tailored to the unique needs of each patient. The Company’s innovative aprevo ® Technology Platform combines proprietary AI-driven software with patient-specific fusion devices to personalize surgical procedures, improve patient outcomes, and reduce complications. For more information, visit carlsmed.com or contact info@carlsmed.com.

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