



FDA Grants Second Breakthrough Device Designation for Carlsmed Technology

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CARLSBAD, Calif.--([BUSINESS WIRE](#))--Carlsmed announced today that the FDA granted Breakthrough Device designation for its aprevo® technology for treatment of patients with cervical spine disease. This is Carlsmed's second Breakthrough Device designation, complementing the company's family of lumbar patient-specific interbody fusion devices for anterior, lateral, and transforaminal approaches.

"Maintenance of sagittal balance after anterior cervical discectomy and fusion procedures is an important parameter to reduce risk for subsequent degeneration at adjacent levels," said Christopher Ames, M.D., director of spinal tumor and spinal deformity surgery at UCSF Medical Center in California. "Using aprevo® personalized interbody devices in conjunction with careful preoperative planning for cervical procedures may help surgeons more reliably achieve the optimal alignment for each individual patient."

Carlsmed's digital technology platform creates one-of-a-kind fusion devices for each patient. The bespoke aprevo® devices are 3D printed, sterile packed, and delivered directly to the hospital for surgery.

"Our goal is to accelerate deployment of patient-centric pioneering technology that revolutionizes the standard of care for spine surgery," said [Mike Cordonnier](#), CEO of Carlsmed. "Expanding the application of our personalized solutions to help patients suffering from cervical spine disease is the next natural step for our portfolio."

More than 350,000 cervical fusion surgeries are performed each year in the U.S., and procedure volume is growing at nearly twice the rate of lumbar fusion surgeries. Carlsmed's aprevo® device for the treatment of cervical spine disease is anticipated to be launched in the U.S. in 2025.

About Carlsmed

Carlsmed's mission is to improve outcomes and decrease the cost of healthcare for spine surgery. The Carlsmed aprevo® personalized surgery platform is designed to improve the standard of care for spine surgery one patient at a time. For more information, visit carlsmed.com or contact us at info@carlsmed.com.

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