

# K2M Spacer System Cleared

Walter Eisner • Thu, Jul 16th, 2009

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K2M's Aleutian Spacer System has received FDA clearance for marketing.

The system is cleared as an intervertebral body fusion device. On July 14 the company reported that the device's radiolucent properties have the potential to increase visualization of bone graft, while allowing for more accurate fusion assessment.



Aleutian Spacer System

The company also believes that elastic modulus, one of the physical properties of the device's material, more closely matches that of cortical bone for load sharing with the potential to minimize stress shielding and enhance fusion results. The bulleted nose allows for easy insertion and distraction, and the self-retaining teeth can potentially provide post-operative stabilization of the implant.

The spacer system is one of five devices in K2M's Aleutian family of systems that offer anatomically designed PEEK-Optima interbody options, including the Anterior-Lumbar Interbody Fusion (ALIF), Small-Anterior (Cervical), Posterior-Lumbar Interbody Fusion (PLIF), Anatomically Narrow (AN), and Transforaminal-Lumbar Interbody Fusion (TLIF).

Raphael Roybal, M.D., an orthopedic spine surgeon at the Savannah Spine Institute added, "The Aleutian family of interbody PEEK cages provides a reproducible bridge where successful arthrodesis crosses over to superior anatomical reconstruction."

President and CEO Eric Major, who recently received the Ernst & Young Entrepreneur of the Year Award for Emerging Technologies in the Greater Washington region, said the clearance allows K2M to offer surgeons multiple surgical applications in the cervical and lumbar spine for the treatment of degenerative disc disease (DDD) and spondylolisthesis."

**Congratulations Eric and happy marketing.**

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