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K2M ALEUTIAN Spacer Systems Receive FDA Clearance to be Marketed as Intervertebral Body Fusion Devices

LEESBURG, VA…July 14, 2009 – K2M, Inc., a spinal device company developing innovative solutions for the treatment of complex spinal pathologies, today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its ALEUTIAN® Spacer Systems as intervertebral body fusion devices. The ALEUTIAN family of five different systems offers a full array of 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).

ALEUTIAN features radiolucent properties which have the potential to increase visualization of bone graft, while allowing for more accurate fusion assessment. In addition, the elastic modulus, a physical property of the 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 easier insertion and distraction, and the self-retaining teeth can potentially provide post-operative stabilization of the implant.

According to Dr. Raphael Roybal, Orthopedic Spine Surgeon at the Savannah Spine Institute, “The ALEUTIAN family of interbody PEEK cages provides a reproducible bridge where successful arthrodesis crosses over to superior anatomical reconstruction.”

“FDA clearance for the ALEUTIAN Spacer Systems to be marketed as intervertebral body fusion devices provides surgeons with multiple surgical applications in the cervical and lumbar spine for the treatment of Degenerative Disc Disease (DDD) and Spondylolisthesis, as well as more complex applications,” stated Eric Major, K2M’s President and CEO. “The anatomically designed implants and differentiated surgical instruments facilitate and streamline surgical applications. The ALEUTIAN family of products complements our comprehensive product portfolio of best-in-class systems for treating all types of complex spinal pathologies.”

About K2M

K2M, Inc. is an innovative spinal device company committed to the research, development, and commercialization of simplified solutions for the treatment of complex spinal pathologies and procedures. Chief Medical Officer, Chairman and co-founder, Dr. John Kostuik, former Chief of Spine Surgery at The Johns Hopkins University School of Medicine, drives K2M’s commitment to redefining the market. The company is recognized as a worldwide leader in providing unique technologies for the treatment of deformity, degenerative, trauma, and tumor spinal patients. K2M’s complete portfolio of next generation products includes: spinal stabilization systems, minimally invasive systems, and other advancing technologies such as motion preservation, annular repair, and nucleus replacement. Additional information is available online at www.K2M.com.

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