



K2M Expands Minimally Invasive Spine Portfolio With Addition of Its CASCADIA™ Lateral Interbody System Featuring Lamellar Titanium Technology™

First Surgical Case Using CASCADIA Lateral Completed Following Receipt of FDA 510(k) Clearance and a CE Mark

LEESBURG, Va., Jan. 08, 2016 (GLOBE NEWSWIRE) -- [K2M Group Holdings, Inc.](#) (Nasdaq:KTWO), a global medical device company focused on designing, developing and commercializing innovative and proprietary complex spine technologies, techniques and minimally invasive procedures, today announced it has recently received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market the [CASCADIA™ Lateral Interbody System](#) featuring [Lamellar Titanium Technology™](#), the Company's innovative and proprietary technology that uses 3D printing with the goal of allowing for bony integration throughout an implant. In addition to U.S. regulatory clearance, K2M also received a CE Mark for the system, which allows the Company to expand the global availability of the product.

K2M's Lamellar Titanium Technology uses an advanced 3D printing method to create structures that were once considered impractical with traditional manufacturing techniques. Starting with a titanium powder, the implants are grown through the selective application of a high-energy laser beam, allowing for the incorporation of both a porosity and surface roughness that pre-clinical data have associated with bone growth activity.*

"By incorporating the porosity and rough surfaces of the Lamellar Titanium Technology into the CASCADIA Lateral interbodies, an alternative now exists to the traditional PEEK and Titanium cages commonly used in direct lateral fusion procedures," stated Dr. Pierce Nunley, director of the Spine Institute of Louisiana, who completed the first surgical case using CASCADIA Lateral in December 2015. "The design of the CASCADIA Lateral implant offers me a greater bone graft volume than my normal ALEUTIAN® PEEK implant, while increasing the endplate contact surface area and still allowing me the ability to radiographically evaluate the fusion."

K2M's Lamellar Titanium Technology incorporates titanium with a surface roughness of 3-5 microns and is designed to allow for direct bony ongrowth.* The technology also incorporates 500 micron longitudinal channels throughout the implant which, in conjunction with traverse windows, create an interconnected lattice designed to allow for bony integration.* Lamellar Titanium Technology exploits the material properties of titanium in conjunction with a product design that incorporates an approximately 70% porosity to mitigate the device's radiographic signature.

The CASCADIA Lateral Interbody System features a reverse hourglass implant design that allows for increased endplate contact compared to an ALEUTIAN implant and without sacrificing internal bone graft volume. The system includes a full range of implant sizes and is designed to work in conjunction with the [RAVINE® Lateral Access System](#), offering a full line of instrumentation for the far lateral transpoas approach.

"We are pleased to receive FDA 510(k) clearance and a CE Mark for the CASCADIA Lateral Interbody System, further expanding the offering of our proprietary Lamellar Titanium Technology, which uses 3D printing and is designed to allow for bony ongrowth and ingrowth," stated Eric Major, K2M's President and CEO. "These regulatory milestones, coupled with the successful completion of the first surgical case late last year, underscore our commitment to expanding our minimally invasive spine portfolio by bringing innovative and differentiated technologies and products to the global spine market."

CASCADIA Lateral is K2M's third product to feature its Lamellar Titanium Technology. The Company also received FDA 510(k) clearance and a CE Mark for the CASCADIA [AN](#) and [TL](#) Interbody Systems in 2015.

For more information on Lamellar Titanium Technology, the CASCADIA Interbody Systems, and K2M's complete product portfolio, visit www.K2M.com.

** Supporting literature and data on file. Pre-clinical data may not represent clinical results.*

About K2M

K2M Group Holdings, Inc. is a global medical device company focused on designing, developing and commercializing innovative complex spine and minimally invasive spine technologies and techniques used by spine surgeons to treat some of the most difficult and challenging spinal pathologies. K2M has leveraged these core competencies to bring to market an increasing number of products for patients suffering from degenerative spinal conditions. These technologies and techniques, in combination with a robust product pipeline, enable the Company to favorably compete in the global spinal surgery market. Additional information is available online at www.K2M.com.

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Forward-Looking Statements

This press release contains forward-looking statements that reflect our current views with respect to, among other things, our operations and financial performance. Forward-looking statements include all statements that are not historical facts. In some cases, you can identify these forward-looking statements by the use of words such as "outlook," "believes," "expects," "potential," "continues," "may," "will," "should," "could," "seeks," "predicts," "intends," "plans," "estimates," "anticipates" or the negative version of these words or other comparable words. Such forward looking statements are subject to various risks and uncertainties including, among other things: our ability to achieve or sustain profitability; our ability to successfully demonstrate the merits of our technologies; pricing pressure from our competitors, hospitals and changes in third-party coverage and reimbursement; competition and our ability to develop and commercialize new products; aggregation of hospital purchasing from collaboration and consolidation; hospitals and other healthcare providers may be unable to obtain adequate coverage and reimbursement for procedures performed using our products; the safety and efficacy of our products is not yet supported by long-term clinical data; our dependence on a limited number of third-party suppliers; our ability to maintain and expand our network of direct sales employees, independent sales agencies and international distributors; the proliferation of physician-owned distributorships; concentration of sales from a limited number of spinal systems or products that incorporate these technologies; loss of the services of key members of our senior management, consultants or personnel; ability to enhance our product offerings through our research and development efforts; failure to properly manage our anticipated growth; acquisitions of or investments in new or complementary businesses, products or technologies; ability to train surgeons on the safe and appropriate use of our products; requirements to maintain high levels of inventory; impairment of our goodwill or intangible assets; disruptions in our information technology systems; any disruption in operations at our headquarters facility or an ability to ship a sufficient number of our products to meet demand; ability to strengthen our brand; fluctuations in insurance cost and availability; extensive governmental regulation; failure to obtain or maintain regulatory approvals and clearances; requirements for new 510(k) clearances, premarket approvals or new or amended CE Certificates of Conformity; medical device reporting regulations, voluntary corrective actions or agency enforcement actions; a recall of our products or the discovery of serious safety issues with our products; possible enforcement action if we engage in improper marketing or promotion of our products; the misuse or off-label use of our products; delays or failures in any future clinical trials; the results of clinical trials; procurement and use of allograft bone tissue; environmental laws and regulations; compliance by us or our sales representatives with fraud and abuse laws; U.S. legislative or regulatory healthcare reforms; medical device tax provisions in the healthcare reform laws; our need to generate significant sales to become profitable; potential fluctuations in sales volumes and our results of operations may fluctuate over the course of the year; uncertainty in our future capital needs; continuing worldwide economic instability; our inability to protect our intellectual property rights; our reliance on patent rights that we either license from others or have obtained through assignments; our patent litigation; the outcome of potential claims that we, our employees, our independent sales agencies or our distributors have wrongfully used or disclosed alleged trade secrets or are in breach of non-competition or non-solicitation agreements with our competitors; potential product liability lawsuits; operating risks relating to our international operations; our ability to comply with the Foreign Corrupt Practices Act and similar laws associated with our activities outside the United States; control by and possible conflicts of interest with our controlling shareholder; increased costs and additional regulations and requirements as a result of becoming a public company; our ability to implement and maintain effective internal control over financial reporting in the future; the potential impact of any future acquisitions, mergers, dispositions, joint ventures, investments or other strategic transactions we may make; and other risks and uncertainties, including those described under the section entitled "Risk Factors" in our Annual Report on Form 10-K filed with the SEC on March 18, 2015, as such factors may be updated from time to time in our periodic filings

with the SEC, which are accessible on the SEC's website at www.sec.gov. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included in this release and our filings with the SEC.

We operate in a very competitive and challenging environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this release. We cannot assure you that the results, events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

The forward-looking statements made in this press release relate only to events as of the date on which the statements are made. We undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward looking statements and you should not place undue reliance on our forward-looking statements.

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