



K2M Receives CE Mark for Its Next-Generation RHINE™ Cervical Disc System

K2M's Cervical Artificial Disc Replacement Features Proprietary Molding Technology to Minimize Wear Between Polymer Core and Metal Endplates

LEESBURG, Va., Jan. 21, 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 and techniques, today announced it has received a CE Mark for the RHINE™ Cervical Disc System, allowing for sale and distribution of the product within Europe and other countries. The RHINE Cervical Disc is the Company's next-generation cervical artificial disc replacement featuring proprietary molding technology and is K2M's latest offering for the treatment of degenerative disc disease.

The RHINE Cervical Disc System features a one-piece compressible polymer core design with dome-shaped, plasma-coated endplates and a central-split keel. Proprietary molding technology is incorporated to minimize wear between the polymer core and metal endplates.

"The RHINE Cervical Disc System is manufactured through a proprietary over-molding process of elastomeric polymer that differentiates the system from the competitive offering," said Dr. Casey Lee, Orthopedic Surgeon and Principal Inventor of the RHINE Cervical Disc System. "We are committed to showing successful clinical results and are initiating a prospective observational clinical study in multiple sites throughout Europe."

The system's streamlined instrumentation simplifies the surgical technique by integrating trialing and keel cutting into one instrument. A built-in adjustable stop allows for customized anterior or posterior positioning of the disc based on surgeon preference.

"The RHINE Cervical Disc System was developed through collaboration with a global surgeon design team," said Dr. Richard Guyer, Orthopedic Surgeon, Co-founder of the Texas Back Institute, and Director of the Spine Fellowship Program in Texas. "The one-piece compressible polymer core design performed well in biomechanical testing when compared to the natural cervical disc, and this European launch represents evolution in cervical disc technology."

The first single- and multi-level surgical procedures using the RHINE Cervical Disc System were recently completed in Belgium and Germany. Additionally, enrollment for a prospective, observational RHINE Cervical Disc Clinical Study will begin in the first quarter of 2016. Primary objectives of the study are to: obtain operative data and feedback; confirm device performance; and collect radiographic data and clinical outcomes. An estimated 166 participants are expected to be enrolled in the study at multiple clinical trial sites throughout Europe.

"We are excited to receive a CE Mark for our RHINE Cervical Disc technology, as it represents an important regulatory milestone event for K2M as we continue to build our product portfolio and penetrate the global spine market with innovative techniques and technologies," stated Eric Major, K2M's President and CEO. "We look forward to further expanding our international product offering and will remain focused on the complex spine category across all of our international markets."

For more information on the RHINE Cervical Disc System and K2M's complete product portfolio, visit www.K2M.com.

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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