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LDR Submits PMA for Mobi-C® Cervical Artificial Disc

Safety and effectiveness results from the single-level IDE clinical study sent to the FDA

AUSTIN, Texas--(BUSINESS WIRE)--LDR, a privately held medical device company offering innovative spinal implants for both non-fusion and fusion applications, announced the January 14th submission of its single-level Mobi-C cervical artificial disc PMA to the FDA. As only one of two companies to have completed enrollment and two year follow-up for one-level and two-level cervical artificial disc replacement studies, LDR has reached another important milestone. "It is extremely satisfying to submit the study results to the FDA and we are very pleased with the preliminary study outcomes," said Christophe Lavigne, president and CEO of LDR. Dr. Michael Hisey, spine surgeon at the Texas Back Institute in Plano, Texas, said, "I feel very fortunate to have been able to participate in the IDE study, and I look forward to having the Mobi-C cervical disc as an approved device option in the future. I am happy with the clinical results of the patients who received the Mobi-C at our center and I feel that cervical disc replacement can be an excellent treatment option."

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Since its introduction in 2004, the Mobi-C cervical disc has been implanted in over 10,000 patients outside the U.S. The IDE study results represent additional clinical evidence to support the eventual use of the Mobi-C cervical disc to treat patients in the United States as well. The company believes that the addition of this innovative cervical non-fusion device to its U.S. product offering will position LDR for continued growth and success in the artificial cervical disc market. Dr. Gregory Hoffman, spine surgeon at SpineONE and president of the Fort Wayne Orthopaedic Society, agrees. "The encouraging clinical results of the Mobi-C IDE study that I have observed will add significantly to the body of evidence supporting cervical spine arthroplasty. There is justified optimism regarding the potential benefits of cervical artificial discs and for Mobi-C in particular." The study data will be submitted by IDE investigators for publication and for presentation at future scientific conferences, including the upcoming ISASS meeting in Las Vegas in April.

The controlled mobility of the Mobi-C polyethylene insert is designed to accommodate the segmental instantaneous axes of rotation, thereby eliminating the need for invasive vertebral anchorage such as screws or keels. System instrumentation is designed to facilitate the straight forward insertion of the device with little disruption to the cervical spine.

LDR works closely with surgeons to develop unique implantable spine devices and instrumentation designed to support the clinical goals of surgery while making procedures easier to perform. More information is located at www.ldrholding.com.

Caution: Mobi-C is not available for use in the United States.

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Contacts

LDR
Joe Ross, 512-344-3410
Vice President of U.S. Marketing
joeross@ldrspine.com