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Ellipse Technologies Receives FDA Clearance for Next Generation of Unique Limb Lengthening System

IRVINE, Calif., February 04, 2014 — Global medical device company, Ellipse Technologies, Inc., has announced that it has received FDA marketing clearance of the PRECICE® 2 Intramedullary Limb Lengthening System in the United States. This marketing clearance represents the most recent advancement of the innovative PRECICE system, originally cleared for use in the U.S. in 2011. The PRECICE system provides a unique solution that allows precisely controlled, noninvasive adjustment of the implant that is unavailable with other treatment options. To date, PRECICE devices have been used in over 700 procedures in 12 countries by more than 100 surgeons. Its initial success has confirmed it as the preferred treatment option for patients with limb length inequality.

The PRECICE 2 system introduces a non-modular intramedullary design to simplify its implantation and provides increased nail length and distraction range options to better optimize treatment options. This system also includes a new smaller diameter (8.5 mm) nail which will address a large segment of patients whose anatomy was too small for the original, larger PRECICE nail devices.

"The introduction of the PRECICE 2 system complements the early success of the PRECICE device with improved efficiency in the OR and the larger range of patients with limb length inequality who can now be treated," said Ed Roschak, President and CEO of Ellipse. "We continue to work every day to apply our platform technology to address unmet needs in orthopedics and spine."

Surgeons Shawn C. Standard, M.D., Head of Pediatric Orthopedics at the International Center for Limb Lengthening at Sinai Hospital in Baltimore, MD, and Dror Paley, M.D., Director of the Paley Advanced Limb Lengthening Institute at St. Mary's Medical Center in West Palm Beach, FL, were the first surgeons in the U.S. to use the PRECICE 2 system.

"Previously, treatment options for patients with limb length inequality were very limited. The PRECICE system has dramatically impacted my practice over the last two years, and, with PRECICE 2, I expect even better results for my patients." said Dr. Standard. Dr. Paley added, "The PRECICE 2 system makes a great device even better and allows me to treat a wider spectrum of patients than before."

The PRECICE 2 system has been granted FDA marketing clearance for limb lengthening of the femur or tibia. This system can be used to correct limb inequality caused by congenital shortening, post-traumatic fractures, and other conditions that result in leg shortening.

About Ellipse Technologies

Ellipse Technologies, Inc. is a privately-held medical device company located in Irvine, California. The Company is dedicated to the design, development, and commercialization of its evolving proprietary technology platform for orthopedic and spinal applications. This technology enables precisely controlled, non-invasive post-operative adjustment of implants allowing surgeons to better address a range of clinical needs. Ellipse Technologies has successfully introduced two implant systems, PRECICE® and MAGEC®, which are used in limb lengthening procedures and in the treatment of scoliosis, respectively. Ellipse is developing additional products to significantly improve clinical outcomes in a variety of applications through its collaboration with surgeon thought leaders. For more information, visit www.ellipse-tech.com.