Cardica Completes Enrollment In European Clinical Trial For Surgical Cutting And Stapling Device

The Associated Press

Cardica, Inc. (Nasdaq: CRDC) today announced it has completed enrollment in the European clinical study for its MicroCutter XCHANGET 30, a cartridge-based cutting/stapling device with a 5-millimeter shaft diameter and cross-sectional area more than six times smaller than standard 12-millimeter surgical staplers used today. The trial is designed to evaluate the safety of the XCHANGE 30 in a variety of gastrointestinal surgical procedures to support a 510(k) filing for market clearance from the U.S. Food and Drug Administration (FDA).

"Based on consistent product performance and positive unaudited clinical outcomes of the trial to date, following standard statistical analyses we expect to file regulatory documents with the FDA in the third quarter of calendar 2013," said Bernard A. Hausen, M.D., Ph.D., president and chief executive officer of Cardica. "We would like to express our sincere thanks to the investigators and patients for their enthusiasm in participating in the trial to advance the XCHANGE 30, the smallest cutting and stapling device available today." The prospective, single-arm, multi-center, non-inferiority clinical study enrolled 160 patients at seven centers in Germany. The results of the procedures will be compared to historical adverse event reports for similar procedures performed with currently available stapling devices. Typical adverse events associated with current surgical staplers include staple line leakage, staple line bleeding, staple line strictures and surgical infections.

About Cardica
Cardica designs and manufactures proprietary stapling and anastomotic devices for cardiac and laparoscopic surgical procedures. Cardica's technology portfolio is intended to minimize operating time and enable minimally-invasive and robot-assisted surgeries. Cardica manufactures and markets its automated anastomosis systems, the C-Port@ Distal Anastomosis Systems and PAS-Port@ Proximal Anastomosis System for coronary artery bypass graft (CABG) surgery, and has shipped over 45,200 units throughout the world. In addition, Cardica is developing the Cardica@ MicroCutter XCHANGET 30, a cartridge-based microcutter device with a five-millimeter shaft diameter, and the Cardica@ MicroCutter XCHANGET 45, a cartridge-based microcutter device with an eight-millimeter shaft. Both MicroCutter devices are designed to be used in a variety of procedures, including bariatric, colorectal, thoracic and general surgery. The Cardica MicroCutter XCHANGE 30 and XCHANGE 45 products require 510(k) review and are not yet commercially available in the U.S.

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