Covidien Receives FDA 510(k) Clearance for Groundbreaking iDrive™ Ultra Powered Stapling System

The Associated Press

NEW HAVEN, Conn.--(BUSINESS WIRE)--Aug 28, 2012--Covidien (NYSE: COV), a leading global provider of healthcare products, announced today that it has obtained 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the iDrive™ Ultra powered stapling system. The new stapling system is the only fully powered, reusable, battery-operated endoscopic surgical stapler in the world. Featuring one-handed push-button operation and unlimited articulation, the system eliminates the need for manual firing force and improves maneuverability, compared with traditional endomechanical staplers.

The iDrive Ultra system is the second offering in Covidien's line of powered stapling devices and the first that is compatible with the Company's entire portfolio of Endo GIA™ reloads with Tri-Staple™ technology for use in laparoscopic and open surgical procedures. The iDrive Ultra system combines the precision and control of a powered device with proprietary Tri-Staple technology that provides less stress on tissue during compression and clamping 1, potentially greater perfusion into the staple line 2 and the ability to manage tissue variability.

"The newest addition to our line of battery-powered devices delivers optimal functionality due to the valuable feedback surgeons have provided," said Paul Hermes, Vice President, Chief Technology Officer, Covidien Surgical Solutions. "We work closely with surgeons to develop products that not only improve patient outcomes, but also make surgery safer, easier and more efficient for surgeons. The iDrive Ultra powered stapling system is another example of Covidien's dedication to innovation and to advancing clinically proven solutions." Hermes continued, "Laparoscopic surgery can be an exceptionally labor-intensive endeavor that requires a high level of accuracy within a very restricted anatomical space. The iDrive Ultra powered stapling system will enable surgeons to operate through restricted anatomical space with greater precision, compared with traditional endomechanical staplers." The iDrive Ultra powered stapling system is designed for multi-patient use, thus streamlining operating room inventory management, and offers an environmentally friendly benefit by reducing medical waste. The system will be available In the U.S. beginning in the fourth quarter of 2012.

ABOUT COVIDIEN Covidien is a leading global healthcare products company that creates innovative medical solutions for better patient outcomes and delivers value through clinical leadership and excellence. Covidien manufactures, distributes and services a diverse range of industry-leading product lines in three segments: Medical Devices, Pharmaceuticals and Medical Supplies. With 2011 revenue of $11.6 billion, Covidien has 43,000 employees worldwide in more than 65 countries, and its products are sold in over 140 countries. Please visit www.covidien.com [1] to

learn more about our business.

1. When compared to Ethicon Echelon Flex™ green reloads as part of a September 2, 2011, analysis comparing different stapler designs and their performance and impact on tissues under compression using two-dimensional finite element analysis.

2. When compared to Ethicon Echelon Flex™ green reloads as part of a bench study conducted August 16-18, 2011, that measured fluid perfusion into clamped media among different stapler designs (Covidien Engineering Report No. PCG-007).

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