SurgiTools Wins FDA 510(k) Clearance for Singh Colpotomizer System

The firm went through pre-market notification with assistance from Emergo Group.

(PRWEB) March 12, 2012 -- SurgiTools Pty Ltd, a Woodvale, Australia-based medical device manufacturer, has obtained 510(k) clearance from the US Food and Drug Administration to sell its Singh Colpotomizer System in the US with assistance from medical device regulatory consultancy Emergo Group.

The Singh Colpotomizer System is designed for use in performing total laparoscopic hysterectomies, and provides enhanced visualization capabilities to surgeons in order to minimize injuries that can occur during laparoscopic procedures.

According to Dr. Jiwan Steven Singh, CEO at SurgiTools, the firm sought third-party support both to meet authorized representation requirements in the US and to manage SurgiTools’ pre-market notification effort with the FDA. Singh ultimately chose Emergo Group as a partner due to his prior experience with the consultancy, and to recommendations from colleagues.

“Emergo Group first helped me to register my other device, the Singh Uterine Positioner,” Singh explains. “It seemed natural to continue the relationship when applying for 510(k) clearance for the Singh Colpotomizer System.”

SurgiTools provided all necessary 510(k) documentation to Emergo Group, which then handled all formatting issues and submitted SurgiTools’ materials to the FDA.

“Smaller-tier, foreign medical device manufacturers such as SurgiTools can find the FDA 510(k) clearance process complicated and time-consuming process,” says Elizabeth Pugh, Regulatory Affairs Consultant at Emergo Group. “By serving as their US agent and managing their pre-market notification effort, we were able to help SurgiTools bring the Singh Colpotomizer System to market in the US faster and more efficiently.”

About SurgiTools
Specializing in total laparoscopic hysterectomies (TLH) and other laparoscopic procedures, SurgiTools has developed the Singh Uterine Positioner and the Singh Active Colpotomizer System to address the obstacles clinicians often encounter when performing laparoscopic operations. Further information at www.surgitools.net

About Emergo Group
Emergo Group is a global medical device regulatory consulting firm providing a wide range of services including FDA consulting and device registration, QMS compliance, clinical trial management, in-country representation, reimbursement and distributor search consulting.

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