



TransEnterix Announces FDA 510(k) Submission for 3mm Senhance Instruments

June 7, 2018

Filed 510(k) submission for 3mm Instruments, advancing minimally invasive capabilities within digital laparoscopy

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--Jun. 7, 2018-- TransEnterix, Inc. (NYSE American:TRXC), a medical device company that is digitizing the interface between surgeons and patients to improve minimally invasive surgery, today announced the Company filed a FDA 510(k) submission for additional Senhance System instruments including 3 millimeter diameter instruments.

The clearance of these instruments would allow the Senhance to be used for microlaparoscopic surgeries, allowing surgeons to make tiny incisions that are deemed virtually scarless for patients.

"TransEnterix is the first company to seek FDA clearance for robotically-driven 3 millimeter instruments for abdominal surgery in the U.S.," said Todd M. Pope, TransEnterix CEO. "We believe Senhance robotic assistance can enable surgeons to expand their use of virtually scarless surgery in more patients, and expands the value that robotics can bring over traditional manual approaches."

"Microlaparoscopy is the current frontier in the process of reducing invasiveness, pain, scarring and opioid use post-surgery," said Dr. Steven D. McCarus, MD, FACOG, Chief of Gynecologic Surgery at Florida Hospital Celebration Health. "With Senhance, robotic microlaparoscopic surgery is a reality, bringing precision, control and sensitive force feedback to the use of these tiny surgical instruments. Surgeons have not had the ability to use such small instruments with a robotic surgical platform before, and this offers patients an attractive, virtually scarless approach to many surgeries."

In the U.S., Senhance is cleared for laparoscopic colorectal, gynecologic, inguinal hernia and cholecystectomy surgery, enabling Senhance to be used in over 3 million procedures per year, including some of the most common abdominal surgeries in general surgery and gynecology.

About TransEnterix, Inc.

TransEnterix is a medical device company that is digitizing the interface between the surgeon and the patient to improve minimally invasive surgery by addressing the clinical and economic challenges associated with current laparoscopic and robotic options in today's value-based healthcare environment. The Company is focused on the commercialization of the Senhance™ Surgical System, which digitizes laparoscopic minimally invasive surgery. The system allows for robotic precision, haptic feedback, surgeon camera control via eye sensing and improved ergonomics while offering responsible economics. The Senhance Surgical System is available for sale in the US, the EU and select other countries. For more information, visit www.transenterix.com.

Forward-Looking Statements

This press release includes statements relating to the Senhance Surgical System and our current regulatory and commercialization plans for this product. These statements and other statements regarding our future plans and goals constitute "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, and are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties that are often difficult to predict, are beyond our control and which may cause results to differ materially from expectations and include whether use of the 3 millimeter instruments will enable surgeons to expand their use of virtually scarless surgery in more patients, and expand the value that robotics can bring over traditional manual approaches. For a discussion of the risks and uncertainties associated with TransEnterix's business, please review our filings with the Securities and Exchange Commission (SEC), including our Annual Report on Form 10-K filed on March 8, 2018 and our other filings we make with the SEC. You are cautioned not to place undue reliance on these forward looking statements, which are based on our expectations as of the date of this press release and speak only as of the origination date of this press release. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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