



TransEnterix Receives FDA Clearance for First Machine Vision System in Robotic Surgery

March 13, 2020

The Intelligent Surgical Unit Enables Augmented Intelligence on the Senhance Surgical System

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)-- TransEnterix, Inc. (NYSE American:TRXC), a medical device company that is digitizing the interface between the surgeon and the patient to improve minimally invasive surgery, today announced the Company received 510(k) clearance for the Intelligent Surgical Unit (ISU™) that enables machine vision capabilities on the Senhance® Surgical System.

"We are pleased to have received this important clearance earlier than expected. Machine vision is the next major advance in digital surgery," said Anthony Fernando, TransEnterix president and CEO. "Our system is designed to significantly advance the sensing capabilities of computer-assisted surgery. With this hardware and software system, the Senhance System will gather and interpret visual information from the surgical field. The capabilities now cleared will be focused on optimizing visualization and camera control in ways never before offered in robotic or digital surgery. These initial capabilities represent the first step in our journey to bring the benefits of augmented intelligence and machine vision to surgery."

The ISU enables machine vision driven control of the camera for a surgeon by responding to commands and recognizing certain objects and locations in the surgical field. The ISU hardware is also designed to be compatible with planned future augmented intelligence features such as scene cognition and surgical image analytics that are expected to continue to drive meaningful innovations in digital laparoscopy with Senhance.

"This is the beginning of a new era in digital surgery," said Dr. Amit Trivedi, chair of surgery at Hackensack Meridian Health Pascack Valley Medical Center and a participant in the design and usability studies conducted in support of the 510(k) submission of the ISU. "Surgery is the skilled real time application of vision, experience, precise motion and decision making. The opportunity to use a computer to see aspects of the field and guide surgery is enormous. I am eager to utilize machine vision to better control the camera seamlessly during my surgeries."

This Intelligent Surgical Unit is compatible with both the global installed base of Senhance Surgical Systems and with third-party vision systems that are currently supported by Senhance.

Senhance Indication for Use

In the U.S., the Senhance® Surgical System is intended to assist in the accurate control of laparoscopic instruments for visualization and endoscopic manipulation of tissue including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, mobilization and retraction. The Senhance Surgical System is intended for use in laparoscopic gynecological surgery, colorectal surgery, cholecystectomy, and inguinal hernia repair. The system is indicated for adult use. It is intended for use by trained physicians in an operating room environment in accordance with the Instructions for Use.

About TransEnterix

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 market development activities for, and increasing utilization of, its 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, Japan and select other countries. For more information, visit www.transenterix.com.

Forward-Looking Statements

This press release includes statements relating to the Senhance System and the Company's 510(k) clearance of its Intelligent Surgical Unit that is designed to enable machine vision capabilities on the Senhance Surgical System. 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 the Intelligent Surgical Unit will be focused on optimizing visualization and camera control in ways never before offered in robotic or digital surgery; and whether the ISU is the beginning of a new era in digital surgery. 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 for the year ended December 31, 2018, filed with the SEC on February 27, 2019 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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Source: TransEnterix, Inc.