



Asensus Surgical Announces 510(k) Submission to FDA for Machine Vision Capabilities Expansion

July 14, 2021

Additional Intelligent Surgical Unit™ features will further extend augmented intelligence leadership in surgery

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--Jul. 14, 2021-- [Asensus Surgical](#), Inc. (NYSE American: ASXC), a medical device company that is digitizing the interface between the surgeon and patient to pioneer a new era of Performance-Guided Surgery™, today announced that it has filed a 510(k) submission with the FDA for an expansion of capabilities on the previously cleared Intelligent Surgical Unit™ (ISU™). The ISU is utilized on the Company's Senhance Surgical System which enables digital laparoscopy.

"The expansion of augmented intelligence capabilities is the next driver of performance in digital surgery," said Anthony Fernando, Asensus Surgical President and CEO. "This submission is an important milestone in our continued leadership with machine vision and augmented intelligence in surgery. We believe these new capabilities will support surgical planning, decision support and teaching."

The current features of the ISU enable machine vision driven control of the camera for a surgeon by responding to commands and recognizing certain objects and locations in the surgical field and allows a surgeon to change the field of view using instruments. The new features would expand to include more advanced features to gather real time data during surgery based on the anatomical structures in the surgical field.

"I am enthusiastic about the new capabilities which will soon be added to the Senhance Surgical System," said Dr. Amit Trivedi, chair of surgery at Hackensack Meridian Health Pascack Valley Medical Center. "These new features would provide planning tools that haven't existed before in digital and robotic surgery and allow me to perform more consistent surgery."

About Asensus Surgical, Inc.

Asensus Surgical, Inc. is digitizing the interface between the surgeon and patient to pioneer a new era of Performance-Guided Surgery by unlocking the clinical intelligence to enable consistently superior outcomes and a new standard of surgery. This builds upon the foundation of Digital Laparoscopy with the Senhance Surgical System powered by the Intelligent Surgical Unit™ (ISU™) to increase surgeon control and reduce surgical variability. With the addition of machine vision, augmented intelligence, and deep learning capabilities throughout the surgical experience, we intend to holistically address the current clinical, cognitive and economic shortcomings that drive surgical outcomes and value-based healthcare. Learn more about Performance-Guided Surgery and Digital Laparoscopy with the Senhance Surgical System here: www.senhance.com. For a complete list of indications for use, visit: www.senhance.com/indications. For more information, visit www.asensus.com.

Forward-Looking Statements

This press release includes statements relating to the Senhance Surgical System and our 510(k) submission to FDA for machine vision capabilities expansion. 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 FDA will clear this 510(k) submission, whether expansion of augmented intelligence capabilities will be the next driver of performance in digital surgery, whether these new capabilities will support surgical planning, decision support and teaching and whether the new features included in the 510(k) submission would expand to include more advanced features to gather real time data during surgery based on the anatomical structures in the surgical field. For a discussion of the risks and uncertainties associated with the Company'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, 2020, filed with the SEC on March 11, 2021 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.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20210714005287/en/): <https://www.businesswire.com/news/home/20210714005287/en/>

INVESTOR CONTACT:

Mark Klausner or Mike Vallie, 443-213-0499

invest@asensus.com

or

MEDIA CONTACT:

Kristin Schaeffer
CG Life
kschaeffer@cglife.com

Source: Asensus Surgical, Inc.