UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

September 1, 2021
Date of Report (date of earliest event reported)

Asensus Surgical, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**0-19437**	**11-2962080**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

1 TW Alexander Drive, Suite 160
Durham, NC 27703
(Address of principal executive offices)
919-765-8400
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):
☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol	Name of each exchange on which registered
Common Stock $0.001 par value per share	**ASXC**	**NYSE American**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On September 1, 2021, Asensus Surgical, Inc., a Delaware corporation (the "Company"), issued a press release announcing that it has received 510(k) clearance from the FDA for an expansion of machine vision capabilities on the previously cleared Intelligent Surgical Unit™ (ISU™). The ISU is utilized with the Company's Senhance® Surgical System which enables Digital Laparoscopy.

A copy of the press release is filed herewith as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibit

Exhibit No.	Description
99.1	Press release dated September 1, 2021
104	Cover Page Interactive Data File (formatted in inline XBRL)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: September 1, 2021

ASENSUS SURGICAL, INC.

By: /s/ Shameze Rampertab

Shameze Rampertab

Executive Vice President and Chief Financial Officer

Exhibit 99.1

Asensus Surgical Receives FDA 510(k) Clearance for Expansion of Machine Vision Capabilities

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

Image Caption: The Senhance Surgical System pictured with the latest ISU model that includes expanded augmented intelligence features such as 3D measurement and enhanced camera control.

RESEARCH TRIANGLE PARK, N.C.-- September 1, 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 received 510(k) clearance from the FDA for an expansion of machine vision capabilities on the previously cleared Intelligent Surgical Unit™ (ISU™). The ISU is utilized with the Company's Senhance® Surgical System which enables Digital Laparoscopy.

"We are thrilled to have received FDA clearance for our next generation of augmented intelligence features on the ISU," said Anthony Fernando, Asensus Surgical President and CEO. "The addition of these pioneering digital capabilities on our existing surgical platform provides real-time intraoperative digital tools to surgeons and underscores our commitment to delivering our vision for Performance-Guided Surgery. This is the latest example of our progress toward delivering on our Surgical Assurance Framework by unlocking the clinical intelligence necessary to enable consistently superior outcomes and a new standard of surgery."

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 allow a surgeon to change the visualized field of view using the movement of their instruments. The newest ISU features expand upon these capabilities and introduce more advanced features including: 3D measurement, digital tagging, image enhancement, and enhanced camera control based on real-time data from anatomical structures while performing surgery. This will be the first time any of these features will be clinically available in soft-tissue abdominal surgery.

"This is a new era in digital surgery," said Dr. Amit Trivedi, chair of surgery at Hackensack Meridian Health Pascack Valley Medical Center and an active user of the Senhance ISU with over one hundred cases completed utilizing the ISU. "The ability to intraoperatively measure with millimeter accuracy in real-time, place digital tags and know that the system keeps track of the instruments at all times are game-changers in surgery. I am very excited about these new features and the future innovations of the ISU's digital technologies for surgeons."

“Utilizing real-time 3D measurement tools would be valuable to evaluate margins and estimate defect sizing,” said Dr. Michael Cook of University Medical Center - New Orleans. “Digital tagging is a major advancement to pinpoint specific anatomical locations during the course of a complex operation that may be utilized as landmarks and teaching aides. Surgical robots have the potential to become decision support tools, and these new features help realize that potential.”

The 3D measurement feature enables the surgeon to use their instruments to designate points on the tissue floor to determine both straight-line distances as well as true topographic distances over the folds and recesses of the abdominal cavity. In traditional minimally invasive surgery, such measurements are estimated or require the use of a sterile measuring tape inside the abdominal cavity. Now 3D measurement allows for accurate readings to millimeter-level accuracy that can assist in various surgical tasks, such as the sizing of hernia mesh or the planning of a staple line. These measurement capabilities represent the first time surgeons have the ability to acquire accurate, real-time measurements without the need for additional tools.

Digital tagging introduces a new surgeon capability to make dynamic annotations on the live surgical camera view for real-time guidance and planning. Further, real-time underlying anatomy monitoring allows tags to persist through intraoperative camera movement. This has the potential to gain procedural efficiencies and delivers dynamic digital markers which preserves the tag locations while tissue is being manipulated.

Image enhancement dynamically adjusts the brightness and contrast of the surgical scene to provide a clear and consistent image, adaptively compensating for uneven illumination. Image enhancement facilitates high-quality video acquisition, which is a cornerstone of Performance-Guided Surgery. Because this feature is vision system agnostic, this benefit can be realized with all vision systems that are compatible with Senhance.

Enhanced camera control builds on existing methods of instrument-based camera control and directs camera positioning based on the tracked location of multiple instruments within the scene and allows for automatic adjustment of pan and zoom simultaneously to maintain visualization of the instruments. Always maintaining visualization of instruments in the field of view is a best practice for performing safe surgery.

The clearance of these expanded augmented intelligence features demonstrates the Company's commitment to delivering on the promise of Performance-Guided Surgery. The Company believes these additional features will provide meaningful support for surgeons across a range of specialties and procedures. Additionally, the foundational elements of these features will enable the Company to continue introducing novel augmented intelligence features in the future by leveraging the vast capabilities and potential of the ISU.

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 the FDA 510(k) clearance for expansion of machine vision capabilities. 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 additional ISU features will further extend augmented intelligence leadership in surgery, whether the expanded ISU features, including 3D measurement, digital tagging, image enhancement and enhanced camera control based on real-time data from anatomical structures while performing surgery will be the first time to be clinically available in soft-tissue abdominal surgery and whether the ISU's additional features will provide meaningful support for surgeons across a range of specialties and procedures. 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.

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