



# SS Innovations (Nasdaq: SSI)



**Advanced. Affordable. Accessible.**  
Robotic Surgery.



# SS Innovations Submits 510(k) Premarket Notification to the **FDA**

**What:** The SSi Mantra Surgical Robotic System.

**When:** Submitted on December 5, 2025.

**Where:** To the United States Food and Drug Administration (FDA).

**For:** A broad range of specialty procedures, including:

- General Surgery
- Urological Surgery
- Colorectal Surgery
- Gynecological Surgery
- Cardiac Surgery



# A Strategic Milestone for U.S. Market Entry

“ *Our submission of a 510(k) premarket notification to the FDA marks an important milestone in our strategic plan to introduce the Company’s advanced, cost-efficient SSi Mantra surgical robotic system to the U.S. market.* ”

**Dr. Sudhir Srivastava**

Chairman of the Board & Chief Executive Officer, SS Innovations



Advanced & Cost-Efficient



Proven Performance



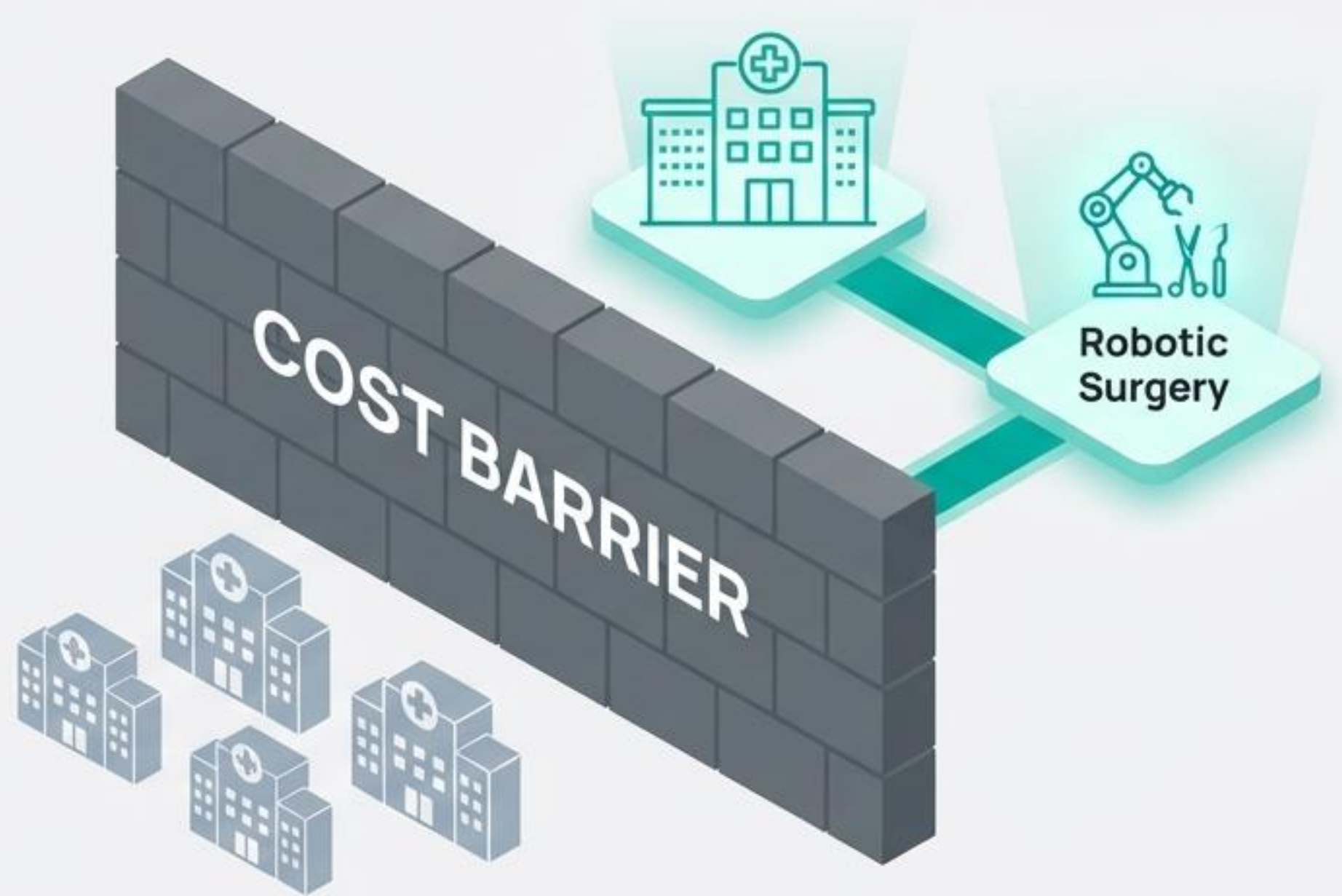
Serving Underserved  
Communities



# The Challenge: High Costs Limit Access to Advanced Robotic Surgery

Robotic surgery offers significant benefits, but its adoption is often hindered by substantial capital investment and high per-procedure costs.

This creates a barrier for many hospitals and health systems, particularly those serving less affluent or rural communities.





# Our Solution: The SSi Mantra System



## Advanced

State-of-the-art, feature-rich technology designed for a wide range of complex procedures, including cardiac surgery.

## Affordable

Engineered to be cost-efficient, lowering the barrier to entry and enabling a faster return on investment for healthcare providers.

## Accessible

Fulfilling our mission to bring the benefits of robotic surgery to a larger segment of the global population.

# Global Validation & Significant Clinical Traction

138

Systems Installed

137

Hospitals



7,300+

Surgical Procedures Performed

Data Source: As of November 30, 2025



# A Diverse and Complex Procedural Experience

The SSi Mantra has been clinically validated in India across more than 100 different types of surgical procedures.



## 390 Cardiac Procedures

Demonstrating capability in one of the most demanding surgical specialties.



## 88 Telesurgeries

Highlighting advanced remote-surgery capabilities and system connectivity.



## 40+ Endo-Surgical Instruments

Supporting a comprehensive range of surgical needs with our proprietary SSi Mudra suite.



# The Surgeon Command Center: Ergonomics Meets Precision Control



**Open-Faced Ergonomic Design**  
For surgeon comfort and communication.

**Large 3D 4K Monitor**  
Delivers an immersive, high-fidelity surgical view.

**Diagnostic Image Superimposition**  
Ability to overlay 3D models from scans onto the live view.

**Touch Panel Monitor**  
Centralized display for all critical patient information.



# The Patient-Side System: Modular, Flexible, and Precise

## Modular 3-to-5 Arm Configuration

Adaptable for different procedural complexities.

## Shared 3D 4K Vision Cart

The entire table-side team sees what the surgeon sees, improving safety and efficiency.

## Virtual Real-Time Arm Imaging

A digital representation of the patient-side carts for enhanced spatial awareness.

## SSi Mudra Instrument Suite

Supported by over 40 types of proprietary robotic instruments.





# A Deliberate and Efficient Pathway to U.S. Approval



**Chosen Pathway:** 510(k) submission selected after pre-submission meetings and discussions with the FDA.

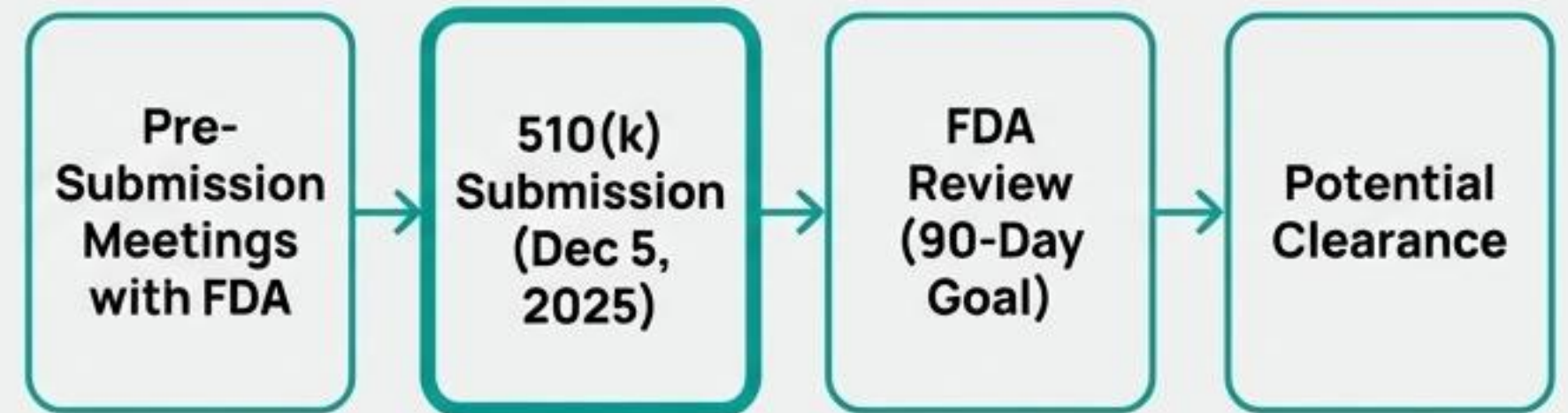


**Strategic Advantage:** This pathway offers potential speed and cost efficiencies compared to a De Novo request.



**FDA Timeline:** The FDA's stated goal is to complete 510(k) reviews within 90 days of receipt.

Disclaimer: Time to approval could be longer due to factors such as the 15-day acceptance review, requests for additional information, and the submitter's response time.





# Expanding Our Global Regulatory Footprint



## United States (FDA)

- **Status:** 510(k) submitted **Dec 5, 2025**.
- **Next Steps:** Awaiting FDA review and clearance.



## European Union (CE)

- **Status:** Actively pursuing CE marking certification.
- **Anticipated Timeline:** Certification expected in the **first half of 2026**.



# SS Innovations (**Nasdaq: SSII**): A Compelling Opportunity in Robotic Surgery

1

## Proven Technology & Global Traction

The SSi Mantra is a mature, clinically validated system with 138 installations and over 7,300 procedures performed globally.

2

## Significant U.S. Market Opportunity

Positioned to address the large, underserved market segment seeking advanced, cost-efficient robotic surgery solutions.

3

## Clear Regulatory & Commercial Path

FDA 510(k) submission complete, providing a clear path to the U.S. market, complemented by a parallel EU strategy.



# About SS Innovations International, Inc.

**Ticker:** Nasdaq: **SSII**

## **Mission:**

To make the benefits of robotic surgery affordable and accessible to a larger segment of the global population.

## **Company Identity:**

An American company headquartered in India.

## **Product Portfolio:**

SSi Mantra Surgical Robotic System and the SSi Mudra suite of surgical instruments.

**Website:** [ssinnovations.com](https://ssinnovations.com)



Follow SS Innovations for updates.



# Contact Information

## Investor Contact

The Equity Group

**Kalle Ahl, CFA**

T: (303) 953-9878

kahl@theequitygroup.com

**Devin Sullivan, MD**

T: (212) 836-9608

dsullivan@theequitygroup.com

## Media Contact

RooneyPartners LLC

**Kate Barrette**

T: (212) 223-0561

kbarrette@rooneypartners.com



# Forward-Looking Statements

This press release may contain statements that are not historical facts and are considered forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. The words “anticipate,” “assume,” “believe,” “estimate,” “expect,” “will,” “intend,” “may,” “plan,” “project,” “should,” “could,” “seek,” “designed,” “potential,” “forecast,” “target,” “objective,” “goal,” or the negatives of such terms or other similar expressions to identify such forward-looking statements. These statements relate to future events or SS Innovations’ future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements.