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SS Innovations files US FDA 510(k) for homegrown surgical robot SSII Mantra

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Marks major leap for indigenous MedTech on global stage

Gurugram-based startup SS Innovations International, Inc. (SSII), India's homegrown surgical robotics pioneer, has announced a landmark milestone with the submission of its 510(k) premarket notification to the US Food and Drug Administration (FDA) for the company's next-generation SSi Mantra surgical robotic system.

The submission covers multiple high-demand surgical specialties, including general, urological, colorectal, gynaecological, and cardiac procedures.

The move marks one of the most significant global regulatory steps ever undertaken by an Indian developed surgical robotic platform, positioning India prominently in a sector long dominated by international players.

Dr Sudhir Srivastava, Founder, Chairman, and CEO of SS Innovations, stated, "Submitting our 510(k) notification to the FDA is a defining moment, not only for SS Innovations, but for India's emergence as a global leader in advanced medical technologies. The SSi Mantra is designed to be affordable, accessible, and technologically differentiated, and its proven performance across diverse geographies speaks for itself. We believe all hospitals, particularly those serving underserved communities, stand to benefit immensely from an option that is both world-class and cost-effective."

Following a pre submission meeting and detailed consultations with the FDA, the Company opted for the 510(k) pathway over a De Novo request, seeking to leverage the route's potential speed and efficiency. The FDA's target review timeline for 510(k) submissions is 90 days, though total review duration may vary. SS Innovations also continues to advance toward its European Union CE Marking, expected in the first half of 2026, further accelerating the global footprint of the Made-in-India platform.