



Da Vinci 5 Cleared for Cardiac Procedures

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FDA 510(k) clearance expands da Vinci 5 indications to include certain cardiac procedures

SUNNYVALE, Calif., Jan. 26, 2026 (GLOBE NEWSWIRE) -- Intuitive (NASDAQ: ISRG), a global technology leader in minimally invasive care and the pioneer of robotic-assisted surgery, today announced that the U.S. Food and Drug Administration (FDA) has cleared the da Vinci 5 system for certain cardiac procedures, including mitral valve repair and IMA (internal mammary artery) mobilization for cardiac revascularization.

Cardiovascular disease remains the leading cause of death worldwide, claiming nearly 18 million lives each year.ⁱ More than two million patients worldwide undergo open heart surgery annuallyⁱⁱ, with most procedures requiring a sternotomy, an approach that involves splitting the breastbone to open the chest and access the heart.

"Opening the chest to perform surgical procedures can involve significant pain, high risk of complications, and long recovery times that can affect patients' physical and psychological wellbeing," said Intuitive chief executive officer Dave Rosa. "This clearance reflects our commitment to advancing minimally invasive cardiac surgery so more surgeons and care teams can pursue improved outcomes for their patients."

Cardiac surgery was the first specialty cleared on the original da Vinci System in 2002. Since then, more than 140,000 robotic-assisted cardiac procedures have been performed using da Vinci systems across 51 countries. While early milestones demonstrated clinical potential, a combination of technical limitations of first-generation platforms and the absence of a global training and support infrastructure led Intuitive to shift its primary focus away from cardiac surgery. Today, with those barriers addressed and a mature ecosystem in place, minimally invasive cardiac surgery is positioned for meaningful expansion with da Vinci 5.

The design of da Vinci 5 can support minimally invasive cardiac procedures by enabling surgeons to operate through small incisions without opening the breastbone. The system offers:

- **10,000x computing power** for future innovation and digital solutions.
- **Smart instrumentation** capturing 1,000+ data points per second.
- **Advanced imaging** for enhanced visualization of vessels and perfusion.
- **An integrated digital ecosystem** supporting the complete journey from pre-operative planning through post-operative analytics.

"Da Vinci 5 marks the beginning of a global initiative to help transform cardiac care," said Intuitive's global vice president of cardiac Darla Hutton. "By combining 30 years of meaningful innovation, structured team-based training programs and a service model built on reliability and safety, we believe we can enable cardiac teams to adopt robotic-assisted surgery in a consistent, scalable and sustainable way."

To support adoption of cardiac surgery with da Vinci 5, Intuitive has established a dedicated team focused on building infrastructure, including the development of bespoke training programs, clinical evidence generation, and cardiac-specific instruments and accessories. A limited number of U.S. sites will begin working with Intuitive through 2026 to establish da Vinci 5 cardiac programs.

Da Vinci 5 is now indicated for the following selected thoroscopically-assisted cardiac surgical procedures using non-force feedback instruments:

- Mitral valve repair
- IMA mobilization for cardiac revascularization
- Patent foramen ovale closure
- Atrial septal defect repair
- Left atrial appendage closure/occlusion
- Atrial myxoma excision
- Mitral valve replacement
- Tricuspid valve repair
- Epicardial pacing lead placement

About Intuitive

Intuitive (NASDAQ:ISRG), headquartered in Sunnyvale, California, is a global leader in minimally invasive care and the pioneer of robotic-assisted surgery. Our technologies include the da Vinci surgical system and the Ion endoluminal system. By uniting advanced systems, progressive learning,

and value-enhancing services, we help physicians and their teams optimize care delivery to support the best outcomes possible. At Intuitive, we envision a future of care that is less invasive and profoundly better, where disease is identified early and treated quickly, so that patients can get back to what matters most.

About da Vinci Surgical Systems

There are several models of the da Vinci surgical system. The da Vinci surgical systems are designed to help surgeons perform minimally invasive surgery and offer surgeons high-definition 3D vision, a magnified view, and robotic and computer assistance. They use specialized instrumentation, including a miniaturized surgical camera and wristed instruments (i.e., scissors, scalpels, and forceps) that are designed to help with precise dissection and reconstruction deep inside the body.

For more information, please visit the company's website at www.intuitive.com.

Important Safety Information

For product intended use and/or indications for use, risks, cautions, and warnings and full prescribing information, visit <https://manuals.intuitivesurgical.com/market>. For summary of the risks associated with surgery refer to www.intuitive.com/safety.

Forward-Looking Statements

This press release contains forward-looking statements which relate to expectations concerning matters that are not historical facts. Statements using words such as "estimates," "projects," "believes," "anticipates," "plans," "expects," "intends," "may," "will," "can," "could," "should," "would," "targeted," "potential," and similar words and expressions are intended to identify forward-looking statements. These forward-looking statements are necessarily estimates reflecting the judgment of Intuitive's management and involve a number of risks and uncertainties that could cause actual results or impacts on its operations, financial performance, and business position to differ materially from those suggested by the forward-looking statements.

These forward-looking statements include, but are not limited to, statements related to research and development of products and services, manufacturing of products, integration of products, obtaining of regulatory approvals, technical and other performance of products and services, and making products and services available to more patients and health care professionals.

These forward-looking statements should be considered in light of various important factors and involve known and unknown risks, uncertainties, and other factors, which may cause the actual results, performance, or achievements of Intuitive, or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Important factors that could cause actual results to differ materially from those anticipated in the forward-looking statements include, among others, economic conditions in the geographic markets in which we operate, changes in governmental regulations, regulatory approval priorities, resources, and timelines, regulatory enforcement priorities, governmental investigations and civil litigation, and other factors discussed in Intuitive's Annual Reports and other filings with relevant securities regulators.

Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release and which are based on current expectations and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those risk factors identified under the heading "Risk Factors" in Intuitive's Annual Report on Form 10-K for the year ended December 31, 2024, as updated by its other filings with the U.S. Securities and Exchange Commission. Intuitive's actual results may differ materially and adversely from those expressed in any forward-looking statements, and it undertakes no obligation to publicly update or release any revisions to these forward-looking statements, except as required by law.

ⁱ World Health Organisation (2025), 'Cardiovascular diseases'. Available at: https://www.who.int/health-topics/cardiovascular-diseases#tab=tab_1

ⁱⁱ National Heart, Lung and Blood Institute (2022). 'Heart Surgery'. Available at: <https://www.nhlbi.nih.gov/health/heart-surgery>

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