



Intuitive Announces FDA Clearance of Revised da Vinci Xi and X Labeling on Radical Prostatectomy

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FDA review of historic data shows patients who received robotic prostatectomies have overall cancer survival rates on par with open surgery

SUNNYVALE, Calif., June 05, 2024 (GLOBE NEWSWIRE) -- Intuitive (NASDAQ:ISRG), a global technology leader in minimally invasive care and the pioneer of robotic-assisted surgery, announced today that the U.S. Food and Drug Administration (FDA) cleared a labeling revision for da Vinci X and Xi specific to radical prostatectomy. This clearance was based on real-world evidence (RWE) collected from 2007 to 2014 that demonstrates overall five- to 10-year survival following robotic-assisted radical prostatectomy is similar to non-robotic radical prostatectomy.

In a public-private collaboration, Intuitive worked with the [FDA](#), [healthcare analytics company Aetion](#), and the [National Evaluation System for health Technology \(NEST\)](#), utilizing its NEST Mark process to support the validity of the real-world data used in the labeling revision submission. This project demonstrated the utility of this type of collaboration in generating high-quality RWE to support marketing applications to the FDA and could allow for similar comprehensive long-term survival assessments for other cancer procedures, which helps advance regulatory science.

"We believe that many robotic procedures have advantages over traditional open surgery and laparoscopy for patients, care teams, and hospital customers—such as shorter hospital stays, fewer conversions, and less blood loss," said Intuitive Chief Medical Officer Myriam Curet, M.D. "This is a significant step because it confirms non-inferiority for overall survival at 10 years for patients undergoing radical prostatectomy with the da Vinci surgical system."

The labeling change applies specifically to the Precaution for Representative Uses statement for the da Vinci X and Xi systems. The previous precaution statement noted that the FDA did not review evaluation of outcomes related to the treatment of cancer. The revised version is as follows (changes in bold):

Precaution for Representative Uses

The demonstration of safety and effectiveness for the representative specific procedures did not include evaluation of outcomes related to the treatment of cancer (overall survival, disease-free survival, local recurrence), **except for radical prostatectomy which was evaluated for overall survival**, or treatment of the patient's underlying disease/condition. Device usage in all surgical procedures should be guided by the clinical judgment of an adequately trained surgeon.

Intuitive provided data from a retrospective cohort study using de-identified healthcare claims data from the Optum Clinformatics Data Mart to evaluate overall survival following radical prostatectomy via robotic-assisted surgery as compared to open surgery among patients with treatment-naive prostate cancer in the U.S. The study evaluation included nearly 25,000 patients, and the timeframe, 2007 to 2014, was chosen to avoid confounding factors related to the COVID-19 pandemic.

About Intuitive

Intuitive (NASDAQ:ISRG), headquartered in Sunnyvale, California, is a global leader in minimally invasive care and the pioneer of robotic 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 important safety information, indications for use, risks, full cautions and warnings, please refer to www.intuitive.com/safety.

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