U.S. FDA Clears da Vinci SP for Certain Transoral Otolaryngology Procedures

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Intuitive's single-port system cleared for radical tonsillectomy and tongue base resection

SUNNYVALE, Calif., March 15, 2019 (GLOBE NEWSWIRE) -- Intuitive (Nasdaq:ISRG), a global technology leader in minimally invasive care and the pioneer of robotic-assisted surgery, today announced it has received clearance for the da Vinci SP® surgical system for use in certain transoral otolaryngology procedures in adults. The FDA cleared the single port approach for lateral oropharyngectomy procedures (commonly referred to as radical tonsillectomy) and tongue base resection.

"Today's FDA clearance means surgeons can utilize da Vinci SP robotic-assisted surgery to conduct radical tonsillectomy and tongue base resection transorally," said Gary Guthart, Intuitive CEO. "Our single port innovation is part of our commitment to helping surgeons and their teams improve patient outcomes, decrease variability in surgery, and improve the patient and surgical team experience."

The da Vinci SP system provides surgeons with robotic-assisted technology designed for deep and narrow access to tissue in the body. The ability to enter the body through a single, small incision or through a natural orifice can provide a minimally invasive experience for complex procedures.

"Intuitive's da Vinci SP complements our other systems by enabling surgeons to access narrow workspaces while maintaining high quality vision, precision, and control that surgeons have come to trust from da Vinci systems," said Guthart.

The da Vinci SP system includes three, multi-jointed, wristed instruments and a fully wristed 3D HD camera. The instruments and the camera all emerge through a single cannula and are properly triangulated around the target anatomy at the distal tip to avoid external instrument collisions that can occur in narrow surgical workspaces. The system enables flexible port placement and excellent internal and external range of motion (e.g., 360-degrees of anatomical access) through the single SP arm. Surgeons control the fully articulating instruments and the camera on the da Vinci SP system, which uses the same surgeon console as the da Vinci X® and Xi ™ systems.

Transoral otolaryngology procedures represent the second category of procedures the FDA has cleared for the da Vinci SP surgical system; the FDA cleared the da Vinci SP system for urology procedures in May 2018. Since the initial clearance, Intuitive has shipped 15 da Vinci SP systems in 2018. With this additional indication, Intuitive plans to continue with its measured introduction of the da Vinci SP system in 2019.

About Intuitive Surgical, Inc.

Intuitive (Nasdaq: ISRG), headquartered in Sunnyvale, Calif., is a global technology leader in minimally invasive care and the pioneer of robotic-assisted surgery. At Intuitive, we believe that minimally invasive care is life-enhancing care. Through ingenuity and intelligent technology, we expand the potential of physicians to heal without constraints.

Intuitive brings more than two decades of leadership in robotic-assisted surgical technology and solutions to its offerings, and develops, manufactures and markets the da Vinci® surgical system and the Ion™ endoluminal system.

Surgical Risks

For Important Safety Information, indications for use, risks, full cautions and warnings, please refer to www.intuitive.com/safety.

Forward-Looking Statement

This press release contains forward-looking statements, including statements regarding the da Vinci SP Surgical System and its potential utility. These forward-looking statements are based on current expectations and estimates and involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements. These forward-looking statements should, therefore, be considered in light of various important factors, including, but not limited to, the following: the impact of global and regional economic and credit market conditions on healthcare spending; healthcare reform legislation in the United States and its impact on hospital spending, reimbursement and fees levied on certain medical device revenues; changes in hospital admissions and actions by payers to limit or manage surgical procedures; the timing and success of product development and market acceptance of developed products, including, but not limited to, the recently cleared Ion endoluminal system, da Vinci SP Surgical System and 3rd generation stapling platform; the results of any collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships; procedure counts; regulatory approvals, clearances and restrictions or any dispute that may occur with any regulatory body; guidelines and recommendations in the healthcare and patient communities; intellectual property positions and litigation; competition in the medical device industry and in the specific markets of surgery in which the company operates; unanticipated manufacturing disruptions or the inability to meet demand for products; the results of legal proceedings to which the company is or may become a party; product liability and other litigation claims; adverse publicity regarding the company and the safety of the company's products and adequacy of training; the company's ability to expand into foreign markets; the impact of changes to tax legislation, guidance, and interpretations; and other risk factors under the heading "Risk Factors" in the company's annual report on Form 10-K for the year ended December 31, 2018, as updated by the company's other filings with the Securities and Exchange Commission. Statements using words such as "estimates," "projects," "believes," "anticipates," "plans," "expects," "intends," "may," "will," "could," "should," "would," "targeted" and similar words and expressions are intended to identify forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. The company undertakes no obligation to publicly update or release any revisions to these forward-looking statements, except as required by law.

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