Intuitive Surgical Receives Firefly(TM) FDA Clearance for da Vinci(R) Xi(TM) Surgical System

August 21, 2014 at 12:58 PM EDT

SUNNYVALE, Calif., Aug. 21, 2014 (GLOBE NEWSWIRE) -- Intuitive Surgical, Inc. (Nasdaq:ISRG), the global leader in robot-assisted minimally invasive surgery, today announced the FDA clearance of *Firefly* Fluorescence Imaging for the *da Vinci*® *Xi*™ Surgical System, which provides surgeons with enhanced visualization during minimally invasive surgical procedures. *Firefly* Imaging has been available since 2011 as an optional feature for the *da Vinci*® *Si*™ System, and this clearance means that *Firefly* Imaging will now ship with all *da Vinci Xi* Systems.

This marks the third significant U.S. FDA clearance for products supporting the *da Vinci Xi* System since its U.S. launch in April. The first and second clearances allow the company to market advanced technologies for vessel sealing and stapling for use with the *da Vinci Xi* System. All three technologies were previously cleared for use with the *da Vinci Si* System.

The *Firefly* Imaging System enables real-time visual assessment of vessels, blood flow and related tissue perfusion. It also enables assessment of the major ducts that connect to the gallbladder for transport of bile, a digestive fluid. This assessment is helpful during surgical removal of the gallbladder. The *Firefly* System enables surgeons to switch between standard, visible light and near-infrared imaging during minimally invasive procedures. When a surgeon uses the *Firefly* System in conjunction with an injectable fluorescent dye, tissue with blood flow is highlighted in a green color and tissue without blood flow appears gray in the surgeon's view. The *Firefly* System is intended to be used for biliary duct visualization in conjunction with standard, visible light in bile-duct imaging and where indicated, X-ray examination of the bile ducts during surgery.

"With this latest clearance for the *da Vinci Xi* System, we're fulfilling our promise of providing an expandable technology platform designed to accommodate and seamlessly integrate a range of current technologies in areas such as imaging, advanced instruments and anatomical access," said Frank P. Grillo, Intuitive Surgical Vice President, Marketing and Business Development. "This is a significant technology designed to enhance surgical performance by providing the surgeon with additional visualization capability during surgery, and we are very pleased to bring it to the *Xi* platform,"Grillo added.

In June, Intuitive Surgical received U.S. FDA clearance for the *EndoWrist*® *One* ™ Vessel Sealer instrument for the *da Vinci Xi* System. The *EndoWrist One* Vessel Sealer is a fully wristed instrument designed to enable sealing and cutting vessels up to 7 mm in diameter and tissue bundles that fit in the jaws of the instrument.

In July, Intuitive Surgical also received U.S. FDA clearance for the *EndoWrist*® Stapler 45 and Stapler white, blue and green reloads for use with the *da Vinci Xi* System. With its integrated design for the *da Vinci Xi* System, the *EndoWrist* Stapler is fully controlled by the surgeon using the *da Vinci Xi* System. It provides wristed articulation and *SmartClamp*™ feedback, which detects if the stapler jaws are adequately closed on the tissue prior to firing. The *EndoWrist* Stapler is intended for resection, transection and/or creation of anastomoses (surgical connections between vessels or tissues) in gynecologic, general, urologic and thoracic surgery. Thoracic surgery is a new indication for the *EndoWrist* Stapler, as thoracic surgery is not part of the *EndoWrist* Stapler 45 indications for use for the *da Vinci Si* System.

Intuitive Surgical will continue to seek regulatory clearances to market the *da Vinci Xi* System and its integrated technologies around the world.

For more information about *Firefly* Fluorescence Imaging and the *da Vinci Xi* Surgical System, visit intuitivesurgical.com.

About Intuitive Surgical, Inc.

Intuitive Surgical, Inc. (Nasdaq:ISRG), headquartered in Sunnyvale, Calif., is the global leader in robotic-assisted, minimally invasive surgery. Intuitive Surgical develops, manufactures and markets the *da Vinci*® Surgical System. Intuitive Surgical's mission is to extend the benefits of minimally invasive surgery to those patients who can and should benefit from it.

About the *da Vinci* Surgical System

There are several models of the *da Vinci* Surgical System. The *da Vinci* Surgical Systems are designed to help doctors perform minimally invasive surgery. *da Vinci* Systems are not programmed to perform surgery on their own. Instead, the surgery is performed entirely by a doctor, who controls the system. *da Vinci* Systems offer doctors 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.

Important Safety Information

Serious complications may occur in any surgery, including *da Vinci* Surgery, up to and including death. Risks include, but are not limited to, injury to tissues and organs and conversion to other surgical techniques. If your doctor needs to convert the surgery to another surgical technique, this could result in a longer operative time, additional time under anesthesia, additional or larger incisions and/or increased complications. Individual surgical results may vary. Patients who are not candidates for non-robotic minimally invasive surgery are also not candidates for *da Vinci* Surgery. Patients should talk to their doctors to decide if *da Vinci* Surgery is right for them. Patients and doctors should review all available information on non-surgical and surgical options in order to make an informed decision. Please also refer to www.daVinciSurgery.com/Safety for Important Safety Information.

Indications for Use for the *da Vinci*® *Xi* ™ Surgical System

The Intuitive Surgical Endoscopic Instrument Control System (*da Vinci* Surgical System, Model IS4000) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and

accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Indications for Use for *Firefly* ™ Fluorescence Imaging for the *da Vinci Xi* Surgical System

The *da Vinci*® *Firefly* ™ Imaging System is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The *da Vinci Firefly* Imaging System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct, or common hepatic duct) using near infrared imaging.

Fluorescence imaging of biliary ducts with the *da Vinci Firefly* Imaging System is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.

Indications for Use for *EndoWrist*® Stapler 45 for the *da Vinci Xi* Surgical System

The *EndoWrist*® Stapler 45, Stapler 45 Reloads and other Stapler Accessories are intended to be used with the *da Vinci Xi* Surgical System for resection, transection and/or creation of anastomoses in general, thoracic, gynecologic and urologic surgery. The device can be used with staple line or tissue buttressing materials (natural or synthetic). The Stapler 45 System and Stapler 45 Reloads should not be used on tissue such as the liver or spleen, where tissue compressibility is such that clamping of the instrument would be destructive. Do not use the Stapler 45 System or Stapler 45 Reloads on the aorta.

Indications for Use for *EndoWrist*® *One*™ Vessel Sealer (*EndoWrist* Vessel Sealer) for the *da Vinci Xi* Surgical System

The *EndoWrist*® Vessel Sealer is a bipolar electrosurgical instrument intended for use with the *da Vinci Xi* Surgical System and the ERBE VIO dV electrosurgical generator. It is intended for grasping and blunt dissection of tissue and for bipolar coagulation and mechanical transection of vessels up to 7 mm in diameter and tissue bundles that fit in the jaws of the instrument. The *EndoWrist* Vessel Sealer has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures. The Vessel Sealer is intended for use only with the *da Vinci*-configured ERBE VIO dV generator. Use of the Vessel Sealer with other generators could result in injury to the patient or surgical team, or cause damage to the instrument.

Forward-Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding regulatory clearances to market the *da Vinci Xi* System around the world. These forward-looking statements are necessarily estimates reflecting the best judgment of our management 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 those under the heading "Risk Factors" in our annual report on Form 10-K for the year ended December 31, 2013, as updated from time to time by our quarterly reports on Form 10-Q and our 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. We undertake no obligation to publicly update or release any revisions to these forward-looking statements, except as required by law.

CONTACT: Intuitive Surgical, Inc. (Nasdaq:ISRG)
Corporate Communications
408-523-7337
corpcomm@intusurg.com
http://www.intuitivesurgical.com/
https://twitter.com/IntuSurgNews

Intuitive Surgical, Inc.logo

Intuitive Surgical, Inc.