Intuitive Surgical Comments on Medical Device Reporting Practices

March 14, 2013

SUNNYVALE, Calif., March 13, 2013 (GLOBE NEWSWIRE) -- Intuitive Surgical, Inc. (Nasdaq:ISRG):

In response to general inquiries regarding a recent rise in Medical Device Reports (MDR) filed by Intuitive Surgical, the company explained that the noted rise does not reflect a change in product performance but rather a change in MDR reporting practices.

In September 2012, Intuitive Surgical revised its MDR practices, resulting in increased reports of device malfunction MDRs, the vast majority of which were related to instruments and not to systems. None of these device malfunction MDRs involved reportable injuries or deaths.

"We self-identified the reporting issue, notified the FDA and revised our practices," said Dave Rosa, Senior Vice President, Emerging Procedures and Technologies, Intuitive Surgical.

MDRs can be found in the FDA's MAUDE database, which is updated by FDA regularly. The most common type of report filed under the company's revised MDR practices involves instrument cable breaks. These cable breaks render the instrument non-functional and require an instrument change, which can be accomplished quickly.

The company also made an administrative change in how MDRs previously reported as adverse events were subcategorized. This change has not increased the total number of adverse event reports. This will result in an increase in events in the "serious injury" subcategory and a corresponding decrease in the "other" subcategory. Total adverse event rates have remained low and in line with historical trends.

About Intuitive Surgical's Products

Intuitive Surgical, Inc. (Nasdaq:ISRG), headquartered in Sunnyvale, California, is the global technology leader in robotic-assisted, minimally invasive surgery. Intuitive Surgical develops, manufactures and markets robotic technologies designed to improve clinical outcomes and help patients return more quickly to active and productive lives. Intuitive Surgical's mission is to extend the benefits of minimally invasive surgery to the broadest possible base of patients. Intuitive Surgical — Taking surgery beyond the limits of the human hand™.

About the *da Vinci*® Surgical System

The *da Vinci*® Surgical System is a breakthrough surgical platform designed to enable complex surgery using a minimally invasive approach. The *da Vinci*® Surgical System consists of an ergonomic surgeon console or consoles, a patient-side cart with three or four interactive robotic arms, a high-performance vision system and proprietary *EndoWrist*® instruments. Powered by state-of-the-art robotic and computer technology, the *da Vinci*® Surgical System is designed to scale, filter and seamlessly translate the surgeon's hand movements into more precise movements of the *EndoWrist*® instruments. The net result is an intuitive interface with breakthrough surgical capabilities. By providing surgeons with superior visualization, enhanced dexterity, greater precision and ergonomic comfort, the *da Vinci*® Surgical System makes it possible for more surgeons to perform minimally invasive procedures involving complex dissection or reconstruction. This ultimately has the potential to raise the standard of care for complex surgeries, translating into numerous potential patient benefits, including less pain, a shorter recovery and quicker return to normal daily activities. For more information about clinical evidence related to da Vinci Surgery, please visit www.intuitivesurgical.com/company/clinical-evidence/

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding our medical device reporting practices, related device malfunction filings, product performance and the speed at which instrument changes can be accomplished. 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 the following: the impact of global and regional economic and credit market conditions on health care spending; health care reform legislation in the United States and its implications on hospital spending, reimbursement and fees which will be levied on certain medical device revenues; timing and success of product development and market acceptance of developed products; procedure counts; regulatory approvals, clearances and restrictions; guidelines and recommendations in the health care and patient communities; intellectual property positions and litigation; competition in the medical device industry and in the specific markets of surgery in which we operate; unanticipated manufacturing disruptions or the inability to meet demand for products; the results of legal proceedings to which we are or may become a party; our ability to expand into foreign markets; and other risk factors under the heading "Risk Factors"' in our report on Form 10-K for the year ended December 31, 2012, 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 to reflect events or circumstances after the date of this press release or to reflect the occurrence of unanticipated events.

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