

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934.

Date of Report: July 12, 2004
(Date of earliest event reported)

Intuitive Surgical, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other
jurisdiction of
incorporation)

000-30713
(Commission File
Number)

77-0416458
(IRS Employer
Identification Number)

950 Kifer Road
Sunnyvale, California
(Address of principal executive offices)

94086
(Zip Code)

Registrant's telephone number, including area code: **408-523-2100**

Item 5. Other Events and Regulation FD Disclosure

On July 8, 2004, Intuitive Surgical issued a press release announcing that its da Vinci(R) Surgical System received FDA clearance for cardiac revascularization. A copy of the press release is attached hereto as Exhibit 99.1.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: July 12, 2004

INTUITIVE SURGICAL, INC.

By: /s/ Lonnie M. Smith
Lonnie M. Smith
Chief Executive Officer

EXHIBIT INDEX

Exhibit
99.1 [Press Release of Intuitive Surgical, Inc. dated July 08, 2004](#)

Intuitive Surgical Receives FDA Clearance for Cardiac Revascularization

SUNNYVALE, CA -- July 8, 2004 -- Intuitive Surgical, Inc. (NASDAQ: ISRG), the industry leader in operative surgical robotics, today announced that FDA clearance has now been granted for use of the da Vinci® Surgical System to perform coronary anastomosis during cardiac revascularization. This clearance follows the submission of data from a multi-center clinical trial involving use of the da Vinci Surgical System to perform internal mammary artery anastomosis to the left anterior descending coronary artery. This indication broadens the use of the da Vinci Surgical System, allowing surgeons in the United States to perform coronary artery bypass surgery with small incisions.

Commenting on the clearance, Lonnie Smith President and CEO of Intuitive Surgical said, "We are pleased with the FDA's most recent cardiac clearance for the da Vinci Surgical System which adds cardiac revascularization to the intra-cardiac procedures previously cleared by the agency. U.S. surgeons can now use the da Vinci Surgical System to perform minimally invasive cardiac revascularization offering their patients an attractive alternative to traditional cardiac surgery.

Michael Argenziano, M.D., Assistant Professor of Surgery at the Columbia University College of Physicians and Surgeons, and Director of Minimally Invasive Cardiac Surgery and Arrhythmia Surgery at New York-Presbyterian Hospital, principal investigator for the study said, "With the current FDA clearance, which is based on data obtained in our multi-center trial of endoscopic coronary artery bypass grafting, the da Vinci Surgical System is now available to facilitate a broad range of minimally invasive cardiac surgery, from intracardiac procedures such as valve repair to epicardial procedures such as cardiac revascularization. I am confident that the da Vinci System will become an important part of every cardiac surgeon's technical arsenal, ultimately improving the way we treat patients suffering from cardiovascular disease."

Douglas Murphy, M.D., Chief of Cardiac Surgery at St. Joseph's Hospital of Atlanta, and an investigator in the trial said, "We can now perform robotic cardiac revascularization in its entirety, from internal mammary artery harvest to performing the critical anastomosis with unparalleled precision. This clearance provides better surgical options for our patients while advancing the frontiers of minimally invasive cardiac surgery."

About Intuitive's Products:

The da Vinci Surgical System consists of a surgeon's viewing and control console having an integrated, high-performance InSite® 3-D vision system, a patient-side cart consisting of three or four robotic arms that position and precisely maneuver endoscopic instruments and an endoscope, and a variety of articulating EndoWrist® Instruments. By integrating computer-enhanced technology with surgeons' technical skills, Intuitive believes that its system enables surgeons to perform better surgery in a manner never before experienced. The da Vinci Surgical System seamlessly and directly translates the surgeon's natural hand, wrist and finger movements on instrument controls at the surgeon's console outside the patient's body into corresponding micro-movements of the instrument tips positioned inside the patient through small puncture incisions, or ports.

The Aesop® Endoscope Positioner is a voice-activated robotic arm that automates the critical task of endoscope positioning, providing the surgeon with direct control over a smooth, precise and stable view of the internal surgical field.

The Hermes® Control Center is a centralized system designed to voice control a series of networked "smart" medical devices.

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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: timing and success of product development and market acceptance of developed products; 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 Intuitive Surgical operates; and unanticipated manufacturing disruptions, delays in regulatory approvals of new manufacturing facilities or the inability to meet demand for products. Words such as "estimate," "project," "plan," "intend," "expect," "anticipate," "believe" and similar 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.

Intuitive®, da Vinci®, InSite®, EndoWrist®, Hermes®, and Aesop® are registered trademarks of Intuitive Surgical, Inc.

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