INTUITIVE

Intuitive Surgical's da Vinci Surgical System Receives First FDA Cardiac Clearance for Mitral Valve Repair Surgery

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SUNNYVALE, Calif.--(BUSINESS WIRE)--Nov. 13, 2002--Intuitive Surgical, Inc. (Nasdaq:ISRG), the industry leader in operative surgical robotics, today announced that the U.S. Food and Drug Administration (FDA) has cleared Intuitive's da Vinci(TM) Surgical System for use in mitral valve repair surgery. After reviewing the clinical data from Intuitive's endoscopic (closed chest) mitral valve repair trial, the FDA concluded that the da Vinci Surgical System can be used safely and effectively for minimally invasive mitral valve repair surgery. This intracardiac FDA clearance significantly broadens potential surgical use of the da Vinci System, bringing significant advantages to those hospitals that invest in Intuitive Surgical Systems and to their patients who benefit from robotic surgical treatment.

W. Randolph Chitwood, Jr., M.D., Professor and Chairman of the Department of Surgery at Brody School of Medicine at East Carolina University in Greenville, North Carolina and Principal Investigator of Intuitive's multicenter trial for mitral valve repair, stated: "For the first time, we will be able to offer to a wider range of patients a minimally invasive intracardiac procedure to repair the mitral valve. This news from the FDA will allow more patients to enjoy the benefits of high precision minimally invasive robotic surgery. These benefits include less pain and trauma, shorter hospital stays, quicker recovery and a better cosmetic result."

With this FDA clearance, hospitals can now use the da Vinci Surgical System to perform minimally invasive mitral valve repair surgical procedures. "We are very happy with the FDA's clearance of this additional indication for use for the da Vinci System," said Lonnie Smith, Intuitive's President and CEO. "This clearance for the da Vinci System is the first cardiac clearance by the FDA for any operative robotic system. Our clinical trials have demonstrated that patients clearly benefit from minimally invasive robotic cardiac surgery. This clearance further demonstrates the Food and Drug Administration's commitment to insuring the timely availability as well as the safety and efficacy of new products that bring significant benefits to patients, surgeons and healthcare systems," Smith continued.

The FDA's intracardiac clearance for the da Vinci System does not encompass coronary artery bypass, or "CABG," surgical procedures. Intuitive's multicenter clinical trial for CABG surgery continues to progress.

"At Columbia Presbyterian Hospital, we've performed nearly 100 cardiac surgery cases using the da Vinci System. When using robotics in mitral valve surgery, our post-surgery survey results show an overall increase in patient satisfaction," said Michael Argenziano, M.D., Assistant Professor of Surgery and Director, Cardiac Robotic Surgery at Columbia University in New York City. "Initial results obtained from our post-operative surveys, which included patients from the da Vinci multicenter mitral valve repair trial, unequivocally show that robotic surgery patients have shorter recovery time and improved social functioning, and return to work sooner than patients undergoing traditional surgery."

For surgeons interested in learning more about mitral valve repair surgery with the da Vinci Surgical System, Advocate Christ Medical Center in Oak Lawn, Illinois and Columbia-Presbyterian Medical Center in New York, New York are hosting two full-day events on robotic mitral valve repair surgery featuring live case observations and discussions of their clinical experience. Surgeons interested in attending one of these conferences should call 708-346-4040 to reach Cardiothoracic and Vascular Surgical Associates, S.C at Advocate Christ Medical Center, or 212-305-0991 for the Department of Surgery, Office of External Affairs at Columbia Presbyterian Medical Center.

About Intuitive Surgical's da Vinci(TM) Surgical System

First cleared by the FDA in 1997 for assisting in surgery and in July 2000 for performing actual surgery, the da Vinci Surgical System is still the only robotic system FDA-cleared to perform surgery in multiple specialty areas. Presently, the da Vinci System is FDA-cleared for laparoscopy, thoracoscopy, and now intracardiac mitral valve repair surgery. The system consists of a surgeon's console, a patient-side cart, a high performance 3-D vision system and Intuitive Surgical's proprietary EndoWrist(TM) articulating instruments. By integrating computer-enhanced robotic technology with the technical skills of the surgeon, we believe that our system enables surgeons to perform better surgery in a manner never before experienced. The da Vinci Surgical System seamlessly translates the surgeon's natural hand and wrist movements on instrument controls at the console into corresponding micro-movements of instruments positioned inside the patient through small puncture incisions, or ports.

The da Vinci Surgical System is the only commercially available technology that can provide the surgeon with the intuitive control, range of motion, fine tissue manipulation capability and 3-D visualization characteristic of open surgery, while simultaneously allowing the surgeon to work through the small ports of minimally invasive surgery.

The statements contained in this release may be deemed to contain "forward-looking statements." Such statements are indicated by words or phrases such as "anticipates," "estimates," "projects," "believes," "intends," "expects" and similar words and phrases. Actual results may differ materially from those expressed or implied in any forward-looking statement as a result of certain risks and uncertainties, including, without limitation, competition and market acceptance of the Company's products, ability to obtain regulatory approvals and third- cautioned not to place undue reliance on such forward-looking statements.

Note to Editors: da Vinci(TM), EndoWrist(TM), Intuitive(R) and Intuitive Surgical(R)are trademarks of Intuitive Surgical, Inc.

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