JUSTIFICATION AND APPROVAL
FOR OTHER THAN FULL AND OPEN COMPETITION

1. Contracting Activity: Department of Veterans Affairs
Office of Acquisition Operations
Strategic Acquisition Center
10300 Spotsylvania Avenue, Suite 400
Fredericksburg, VA 22408

2. Description of Action:

The proposed sole source action is for a firm-fixed-price (FFP) contract for procurement of the da Vinci SI Robotic Surgical Systems ("da Vinci system"). The da Vinci system is capable of accommodating a single or dual surgeon console, and associated accessories such as fluorescent imaging, skills practice platform, and replaceable components used during surgery. The procurement will include installation, acceptance testing, training, and a manufacturer's warranty. This effort is proposed to be awarded to the da Vinci system manufacturer, Intuitive Surgical, Inc., 1266 Kifer Road, Sunnyvale, California 94086.

3. Description of Supplies or Services:

Department of Veterans Affairs (VA) Veterans Health Administration (VHA) Medical Centers provide a wide range of surgical services to our Veterans, including traditional surgery, critical care, orthopedics, neurology, oncology, podiatry, urology, and vision care. VA seeks to offer our Veterans advanced surgical techniques comparable to state-of-the-art commercial surgical solutions to include robotic Minimally Invasive Surgery (MIS) procedures. These techniques are proven to reduce the risk of infection, minimize blood loss when compared to traditional procedures, significantly reduce postoperative pain leading to a faster patient recovery time, reduce patient hospital stay, and contribute to positive psychological outcomes as it pertains to postsurgical scarring. The proposed action is to acquire state-of-the-art robotic surgical systems that allow for MIS procedures for a variety of medical conditions. VHA requires a robotic surgical system that can perform urological, laparoscopic, gynecologic, limited transoral otolaryngology, general thoracoscopic, and thoracoscopically assisted cardiotomy procedures.

VHA seeks a robotic surgical system with a multiple surgical uses to expand and/or augment the operational capabilities of VA Medical Centers and medical staff while significantly decreasing the space required to perform those surgeries. The robotic surgical system shall consist of either a single or dual surgeon console which provides the surgeon with intuitive controls, range of motion, fine tissue manipulation capability, and 3-D visualization characteristic of open surgery while simultaneously allowing the surgeon to work through small ports of MIS surgery for the surgical procedures listed above. The dual console will allow for a second surgeon to perform complex surgical procedures that can share controls real-time between two (2) surgeon consoles, or view and monitor the first surgeon console for training purposes. In addition to acquiring the robotic surgical system, VHA requires accessories, and services consisting of installation, training, and manufacturer's warranty.

Any robotic surgical system must be approved for use in the United States by the US Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH), the federal agency responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States. According to 21 Code of Federal Regulations (CFR)

Part 807 Subpart E, a manufacturer cannot commercially distribute medical devices in the United States until the FDA authorizes them to do so.

The total estimated price of this action including the accessories and associated services is $41,039,515.00. Delivery will be phased-in with all deliveries completed within 120 days of the Notice of Award.

4. Statutory Authority:

The statutory authority permitting other than full and open competition is 41 USC.3304(a)(1) as implemented by the Federal Acquisition Regulation (FAR) Subpart 6.302-1 entitled, "Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements."

5. Rationale Supporting Use of Authority Cited Above:

Based on extensive market research, as described in paragraph 8 of this document, the da Vinci system, manufactured by Intuitive Surgical, Inc., is the only robotic surgical system that meets all the requirements of VHA.

Unlike other robotic surgical systems that are on the market, the da Vinci system is the only robotic surgical system that allows surgeons to perform a wide variety of surgical procedures as opposed to only one type of surgery which is critical to VHA requirements. Specifically, the da Vinci system can be used to perform urological, laparoscopic, gynecologic, limited transoral otolaryngology, general thoracoscopic, and thoracoscopically assisted cardiotomy procedures. When the da Vinci system is used, patients experience less trauma and pain, have minimal scarring, faster recovery and a shorter hospital stay, which are all goals for VHA patient care.

Due to the proprietary nature of the da Vinci system and the sole ownership of the patents by Intuitive Surgical, Inc., the only accessories that are interoperable with the system are accessories sold by Intuitive Surgical, Inc. No other robotic surgical accessories are compatible.

Furthermore, the da Vinci system is the only FDA approved robotic surgical system that is capable of performing the VHA required surgeries. FDA classified the da Vinci system as a Class II device, which received a Premarket Notification 510(k) clearance approval pursuant to 21 CFR 807 Subpart E. A 510(k) is a premarketing submission provided to FDA to demonstrate that the device to be marketed is as safe and effective (i.e., substantially equivalent (SE)) to a legally marketed device that is not subject to premarket approval. While market research shows that there are other robotic surgical systems, they are limited to specific types of surgeries, and/or are not FDA approved. With regard to installation, training and the manufacturer's warranty, only Intuitive Surgical, Inc, the sole patent owner, can perform these services due to the proprietary nature of the robotic surgical system.

6. Efforts to Obtain Competition:

Market research was conducted as set forth in paragraph 8 of this document and did not yield any additional sources that can meet the Government's requirements. There is no known competition for this acquisition.

7. Actions to Increase Competition:

The da Vinci system is the only FDA approved robotic surgical system currently on the market that can perform multiple medical surgical procedures as required by VHA. The Government will continue to conduct market research to ascertain if there are changes in the market place that would enable future actions to be competed.

8. Market Research:

Extensive market research was conducted from June 18, 2012 to August 6, 2012 to determine if other potential contractors, specifically small businesses, could meet the robotic surgical system requirement as specified in this Justification and Approval document (J&A) and Statement of Work (SOW).

The overall North American Industry Classification System (NAICS) code was determined to be 339112 (Surgical and Medical Instrument Manufacturing); with the small business size standard of 500 employees.

A search of Service Disabled Veteran-Owned Small Businesses (SDVOSB) and Veteran-Owned Small Businesses (VOSB) under NAICS Code 339112 was conducted on June 25, 2012 at www.vetbiz.gov; Sixty–two (62) SDVOSB and VOSB were identified, but none (based on our review of their product literature at their respective websites) manufactured robotic surgical systems.

A search of the General Services Administration (GSA) Federal Supply Schedule (FSS) was conducted on June 25, 2012. While there are vendors under FSS Special Item Number (SIN) 65 II A (Medical Equipment and Supplies), a review of that section indicated that there were no contractors listed that could supply robotic surgical systems. It was verified that Intuitive Surgical's da Vinci Si System is not available on the GSA FSS.

Sources Sought Notice was posted to www.fbo.gov on July 17, 2012, with response date of July 20, 2012 for capability statements from vendors. No capability statements or inquiries were made in response to this notice. To further ensure that no other manufacturers have a robotic multi-surgical system as required by the VA, an updated Sources Sought Notice seeking sources of robotic surgical equipment to meet VHA requirements was posted on July 30, 2012 with response date from vendors of August 6, 2012. No inquiries or capability statements from vendors or manufacturers were received in response to this notice. A third Sources Sought Notice was posted August 9, 2012 with responses due August 16, 2012. No inquiries or capability statements from any source were received in response to this notice.

An internet search was conducted from June 18, 2012 to August 6, 2012 to confirm whether or not there were other robotic surgical system manufacturers. The search yielded no other immediate, available competitors to Intuitive Surgical, Inc., that would meet the unique, specialized requirements of VHA. Furthermore, research articles on the Internet were reviewed. In these articles, there were references to other manufacturers of robotic surgical systems. However, the review indicated that manufacturers had either not made robotic surgical systems or were manufacturing robotic surgical systems that were limited in scope and focused on one type of surgery/medical treatment (e.g., orthopedic, joint replacement, radiation therapy, etc.) not the array of unique, specialized requirements needed by the VHA in conducting critical patient care of Veterans.

The article *'Open-source' robotic surgery platform going to top medical research labs, Raven II system developed at UC Santa Cruz and University of Washington*, dated January 12, 2012, indicates that the University of Washington and University of California – Santa Cruz have begun work on a Raven II Surgical System that uses an open source model. They have received a grant from the National Science Foundation (NSF) to place these robotic surgical systems at seven universities in the US; however, this system is not available to non-university entities at present, is not FDA approved, and would not be available to meet VHA needs).

The FDA certification of the Intuitive Surgical's da Vinci Si System was verified through the FDA Internet site.

FDA approval is required prior to the use of any medical device (e.g., the Intuitive Surgical's da Vinci Si System). Confirmation that FDA approval is needed was provided by a VHA Chief Biomedical Engineer, who stated that any medical device being used for clinical use must be FDA-approved. The requirement was verified and states:

> **Premarket Notification 510(k) - 21 CFR Part 807 Subpart E**
> If your device requires the submission of a Premarket Notification 510(k), you cannot commercially distribute the device until you receive a letter of substantial equivalence from FDA authorizing you to do so. A 510(k) must demonstrate that the device is substantially equivalent to one legally in commercial distribution in the United States: (1) before May 28, 1976; or (2) to a device that has been determined by FDA to be substantially equivalent.

Market research revealed that no other authorized resellers (preferably small businesses and SDVOSB) could provide the da Vinci system. It was confirmed that Intuitive Surgical, Inc. (via a proprietary rights letter) is the sole manufacturer of this item and its related accessories. There are no authorized re-sellers or dealers of the system or other manufacturers able to compete for this requirement.

As part of the above research and confirmation, additional medical research and robot manufacturing company websites were reviewed and searched to include medicaldevice-network.com; Hansen Medical; Acrobot Company; Curexo Technology Corporation;

On July 26, 2012, an email from the FDA, provided a link to other robotic surgical systems that are FDA-approved as indicated in the table below, but as indicated in the table, the FDA approved robotic surgical systems are limited in scope and cannot perform the array of unique, specialized requirements needed by VHA.

Manufacturer	Device Name	Procedures Approved For
Intuitive Surgical	da Vinci Si System	Urologic surgical procedures, general laparoscopic surgical procedures; gynecological laparoscopic surgical procedures, general cardiovascular and non-cardiovascular thoracoscopic surgical procedures, and thoracoscopically assisted cardiotomy procedures.

Manufacturer	Device Name	Procedures Approved For
Mako Surgical	MAKOplasty	Orthopedic
Hansen Medical	Sensei Surgical System	Specialized robotic catheter system that is controlled by a physician and is designed for accurate positioning, manipulation and stable control of catheter and catheter-based technologies during cardiovascular procedures
Curexo Technology	ROBODOC	Orthopedic

The Buy American Act (41 USC. §§ 10a – 10d) was considered with no compliant sources found.

9. Other Facts:

No other facts are applicable to this J&A.

10. Technical and Requirements Certification:

I certify that the supporting data under my cognizance, which are included in this justification, are accurate and complete to the best of my knowledge and belief.

Name: Edward Witzman Date: 8/14/12

Title: Program Manager Signature:

11. Fair and Reasonable Cost Determination:

I hereby determine that the anticipated price to the Government for this contract action will be fair and reasonable based on comparison of commercial and government pricing.

Name: _____ Date: _____

Procuring Contracting Officer Signature: _____

12. Procuring Contracting Officer Certification:

I certify that this justification is accurate and complete to the best of my knowledge and belief.

Name: PATRICK MCKEOWN Date: 8/14/12

Procuring Contracting Officer Signature:

13. Legal Sufficiency Certification:

I have reviewed this justification and find it adequate to support other than full and open competition and deem it legally sufficient.

Name: Dennis Flory Date: 9/23/12 * subject to a fair and reasonable price determination

Legal Counsel OGC Signature:

Approval

In my role as Executive Director, Office of Acquisition Operations, Agency Competition Advocate, based on the foregoing justification, I hereby approve the acquisition of da Vinci Robotic Surgical Systems, on an other than full and open competition basis pursuant to the statutory authority cited in paragraph 4 above, subject to availability of funds, and provided that the property and services herein described have otherwise been authorized for acquisition.

Date: 9/19/12 Signature: Iris B. Cooper

Iris B. Cooper
Executive Director
Office of Acquisition Operations