

**DEPARTMENT OF VETERANS AFFAIRS**

**Justification and Approval**

**For**

**Other Than Full and Open Competition**

**SAOC-13-01**

1. **Procuring Contracting Activity:** Department of Veterans Affairs, SAO Central Region, 708 S. Third Street, Minneapolis, MN 55417 for the Department of Veterans Affairs, Michael E. DeBakey VA Medical Center, 2002 Holcombe Blvd., Houston, TX 77030.
2. **Nature and/or Description of the Action Being Processed:** Justification and approval for Other Than Full and Open Competition for the purchase of on (1) Da Vinci Surgical System: Si (dual consoles), including installation and training, for the Michael E. DeBakey VA Medical Center, Houston, TX per Purchase Requests # 580-13-3-167-0592. Award of a firm-fixed price contract is anticipated. This procurement will proceed on a sole source basis with Intuitive Surgical, Inc.

The intent of this procurement is to replace and obsolescent system to ensure patient safety and that veterans are provided with the utmost state of the art technology currently found in the private sector. The Contracting Officer's market research has revealed the following:

- a) The primary use of this system will be prostatectomies. Published reports indicate that the incidence of positive surgical margins is statistically lower with robotic radical prostatectomy when compared to traditional surgical procedures.
  - b) Secondary uses of this system include ENT procedures, Thoracic procedures, General Surgery procedures for patients with benign and malignant tumors of the liver, and Gynecology procedures. Published reports indicate that the incidence of complications relating to infection rates and blood transfusions will be much less, resulting in better patient outcomes.
  - c) The Da Vinci system is minimally invasive when compared to traditional surgical methods. As opposed to making larger incisions, this system creates small ports through which the surgeon manipulates the robot to perform the necessary procedure. The benefit to the veteran is less pain and a quicker recovery time. The benefit to the VA is a cost savings by reduced hospital stays for patients (1-3 days as opposed to 3-5 days).
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The Da Vinci Surgical System includes the following items:

System First Surgeon Console: 1 surgeon console, 1 high resolution stereo display, 1 left master controller, 1 right master controller, 1 foot switch panel, 1 surgeon console to vision cart cable, one-year warranty from acceptance date.

System Second Surgeon Console: 1 surgeon console, 1 high resolution stereo display, 1 left master controller, 1 right master controller, 1 foot switch panel, 1 surgeon console to vision cart cable, one-year warranty from acceptance date.

System Patient Cart: 1 patient cart, 1 instrument arm one, 1 instrument arm two, 1 instrument arm three, 1 camera arm, 1 patient cart to vision cart cable, one-year warranty from acceptance date.

System Vision Cart: Includes vision enhancement kit, one-year warranty from acceptance date.

System Documentation: User's manuals for system.

System Software: One-year warranty from acceptance date.

Instrument and Accessories: Includes accessory starter kit (contents subject to change without notice): 1 three arm drape kit, 5 pack, 1 four arm kit, 5 pack, 20 instrument arm drapes, 20 camera head drapes, 20 camera arm drapes, 20 monitor drapes, 1 box of ten 8mm cannula seals, 1 box of three 8mm cannula, 1 cannula gage pin, 1 blunt obturator, 1 box of 24 bladeless obturator, 1 blade protector, 1 Allen wrench, 1 spare lamp module, warranty period 90 days from acceptance date.

Instrument and Accessories (continued): Camera starter kit (starter kit contents subject to change without notice), 1 3D-HD camera head with light guide, 1 camera cable, 1 0 degree endoscope, 1 30 degree endoscope, 1 alignment target, one-year warranty from acceptance date.


Instrument and Accessories: Training instrument starter kit (starter kit contents subject to change without notice), 1 large needle driver, 1 ProGrasp forceps, 1 Maryland Bipolar Forceps, 1 curved scissors, 1 tenaculum forceps, 1 suture cut needle driver, one-year warranty from acceptance date.

The total for all items is \$1,514,500.00. Delivery is expected within 180 days of the Notice of Award.

4. **Statutory Authority Permitting Other than Full and Open Competition**: FAR 6.302-1(a)(2). The VA's minimum needs can only be satisfied by unique supplies or services available from only one source (41 USC 253 (c)(1)).
5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority)**: The operative surgical robotic system manufactured by Intuitive Surgical, Inc. is the only Food and Drug Administration (FDA) approved master-slave robotic surgical system currently available in the commercial market. The system is the only available technology that can provide the surgeon with the 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 minimally invasive surgery. The Food and Drug Administration first cleared the da Vinci Surgical System in 2000 for general laparoscopic surgeries such as gall bladder removal and for treatment of severe heartburn. Since then, use of the system has increased and expanded into several other surgical areas. These include removal of the prostate (radical prostatectomy); non-cardiac chest procedures involving the lungs, esophagus, and a blood vessel inside the chest cavity (internal thoracic artery); and certain procedures involving surgical incisions into the heart, such as mitral valve repair. In April 2005, the FDA cleared the da Vinci system for gynecological laparoscopic procedures. Surgeons are now able to remove the uterus (hysterectomy) and to remove uterine fibroids (myomectomy) using the device. The system has also been cleared for use in all urologic procedures. And, in 2004, the FDA broadened the application of the da Vinci system for assisting in coronary artery bypass surgery. The da Vinci Surgical System is the only operative surgical device of its kind on the market in the United States. In 2003, Intuitive Surgical bought Computer Motion of Goleta, Calif. Computer Motion was the manufacturer of the Zeus Robotic Surgical System, which is no longer actively being marketed.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable**: Considering that the Da Vinci system is the only FDA approved operative surgical robotic system available, efforts to include other potential sources has been limited. This action will be synopsized and published on the Government Point of Entry, FedBizOpps.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable**: The Da Vinci system is currently the only FDA approved surgical robotic system currently on the

market. The Contracting Officer has determined the anticipated cost to be fair and reasonable based on the following information. The vendor, Intuitive Surgical, Inc., has provided a copy of their U.S. Field Sales Team's List of System Prices for the United States which indicates that the price VISN 16 is being charged for their system is the same as the vendor would charge any other customer. *This organization recently awarded a contract for three systems for VISN 11, which reflects that VISN 16 is paying the same amount the VISN 11 facilities paid in 2012 (see attached Market Research).*


8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research has shown that the identified manufacturer is the sole source for this system.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** There are no other facts supporting the use of Other Than Full and Open Competition.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** This J&A will be posted on FedBizOpps. If responses to the synopsis indicate that additional sources are available, the file will be documented accordingly and the requirement competed among all eligible sources.
11. **A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:** None. Until another operative surgical robotic system is approved by the FDA, the Di Vinci system is the only know system capable of meeting the Government's need.
12. **Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

  
COR  
Hayley Raymer  
Program Analyst  
Operative Care Line

7/22/13  
Date

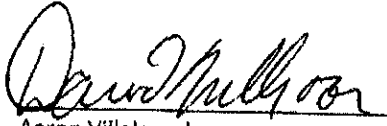
13. **Approvals in accordance with FAR 6.304**

- a. **Contracting Officer's Certification: (required)** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

  
Kenneth J. Shom  
Contracting Officer  
SAO Central Region

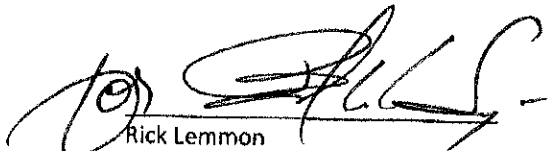
7/22/13  
Date

b. **NCM/PCM:** I certify the justification meets requirements for other than full and open competition.

  
Aaron Villalpando  
Network Contract Manager  
VISN 16

24 July 2013  
Date

c. **SAO:** I certify the justification meets requirements for other than full and open competition.

  
Rick Lemmon  
Director  
Service Area Office, Central

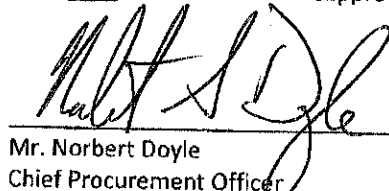
29 Jul 13  
Date

d. **VHA HCA Review and Approval:**

Approved ☒

Disapproved ☐

Amount \$ \_\_\_\_\_

  
Mr. Norbert Doyle  
Chief Procurement Officer  
VHA, Head of Contracting Activity

8/20/13