JUSTIFICATION AND APPROVAL
FOR OTHER THAN FULL AND OPEN COMPETITION

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

2. **Description of Action:**

The proposed contract, with a 12-month base period and four 12-month option periods, is a sole source, firm-fixed-priced requirements contract for the procurement of da Vinci® surgical robots, consumables, warranty, attachments, and other supplies and services related to the da Vinci® surgical system. VHA has previously purchased the da Vinci® Robotic Surgical Systems for 56 medical centers, and this proposed contract will continue the procurement of new systems and provide for the sustainment of existing systems, and includes installation, acceptance testing, training, and all applicable repairs and maintenance. This effort is proposed to be awarded to the da Vinci® system manufacturer, Intuitive Surgical, Inc. (ISI), 1266 Kifer Road, Sunnyvale, California 94086.

3. **Description of the Supplies or Services:**

The 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.

Regarding the procurement of new systems, VHA requires FDA-approved robotic surgical devices to perform Minimally Invasive Surgery (MIS) procedures for the following: urologic, general surgery, gynecological, thoracic, thoracic cardiotomy,

and ear, nose and throat (ENT) surgeries. FDA approved devices are mandated law. VHA also requires a system that is capable of accommodating a single or dual surgeon console and that provide(s) the surgeon(s) with intuitive controls, range of motion, fine tissue manipulation capability, and 3-D visualization characteristic of open surgery while simultaneously allowing work through small ports of MIS surgery, with associated accessories such as fluorescent imaging, skills practice platform, and replaceable components used during surgery.

Regarding sustainment of existing systems, as noted throughout this J&A, the VA has a requirement to maintain the 62 current robotic surgical devices to include providing maintenance, providing necessary accessories, and commodities. Further, all new end-users would have to be provided training on the use of the current operating systems.

The total estimated price of this action including the accessories and associated services is $271,041,375.

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:

VHA currently owns and utilizes 62 da Vinci® systems at 56 separate locations. The da Vinci® robotic system has a robust global presence within VHA. The average age of the existing da Vinci® robotic arm is six years, and the expected lifecycle is six years before planned upgrades. The average number of surgeries performed using the existing systems are 65 per quarter per system. VHA seeks additional robotic surgical systems to expand and/or augment the operational capabilities of VA Medical Centers and medical staff. The forgoing contract expires in July 2019.

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.

Regarding purchase of new equipment for new facilities, the da Vinci® system is the only robotic surgical system that allows surgeons to perform a wide variety of surgical procedures, as opposed to limited types of surgery, which is critical to VHA requirements. Specifically, the da Vinci® system can be used to perform laparoscopic procedures such as prostatectomy, nephrectomy, colectomy, sacrocolpopexy, myomectomy, lobectomy and urological robotic 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.

Regarding sustainment of existing equipment, 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 all of the VHA required surgeries. This was verified as recently as December 2018 by the subject Program Manager for the da Vinci® Robotic device. 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) submission 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 those efforts did not yield any additional sources that can meet the Government's requirements. There is no known competition for this acquisition. The FDA website was extensively searched and only the da Vinci® can perform the different types of surgeries as required by VHA.

7. Actions to Increase Competition:

The anticipated pricing from Intuitive Surgical, Inc., is based on its commercial catalog pricing, which is the same pricing offered to all government buyers. Pricing will be compared against other government contracts and catalog pricing to ensure "fair and reasonable" pricing IAW FAR 15.404-1 (b)(2)(iii). DoD is the single largest buyer of ISI supplies and services. The VA will compare ISI pricing against DoD contracts, as available, and against published pricing lists.

8. Market Research:

Extensive market research was conducted from August 7, 2018 to August 15, 2018 and again on December 10, 2018 to December 12, 2018 to determine if other potential vendors could meet the robotic surgical system requirement as specified in this Justification and Approval document (J&A) and Statement of Work (SOW).

In the abundance of caution, an RFI was posted on FBO numbered 36C10G-19-0029 on December 17, 2018 which closed on January 8, 2019. The RFI sought the names of vendors who manufactured robotic devices that were FDA approved and capable of performing all the surgical procedures as required by the VA. A straightforward chart was provided for vendors to fill-out. That chart is noted below:

Single or Dual Console	Type of Procedures	FDA Approved, Yes/No
	Perform robotic Urological and related procedures	
	Perform robotic General Surgery procedures	
	Perform robotic Gynecological and related procedures	
	Perform robotic Thoracic and related procedures	
	Perform robotic Thoracic Cardiotomy and related procedures	
	Perform robotic laparoscopic and related procedures	
	Perform robotic transoral otolaryngology and related procedures	
	Perform other surgical procedures (describe)	

The RFI received four (4) responses. Out of those four responses, only Intuitive Surgical, the incumbent, is capable of meeting the VA's needs. The latter statement is based upon a review of the material as provided by each vendor in response to the RFI. The four vendors who responded to the RFI were: Alliant Healthcare Products, Fidelis Sustainability Distribution, Stryker d/b/a Mako Surgical Corp., and the incumbent Intuitive Surgical.

A search of the General Services Administration (GSA) Federal Supply Schedule (FSS) was conducted. 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 vendors listed that could supply robotic surgical systems. It was verified that Intuitive Surgical da Vinci® Si System is not available on the GSA FSS.

An internet search was conducted from August 7, 2018 to August 15, 2018 and again on December 10, 2018 to December 12, 2018 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.

The FDA certification of the Intuitive Surgical da Vinci® Si System was verified through the FDA internet site on December 14, 2018. FDA approval is required prior to the use of any medical device (e.g., the Intuitive Surgical 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 in pertinent part:

> **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 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, robot manufacturing company websites were reviewed and searched to include TransEnterix and Titan Medical. To date, the FDA's 510k directory indicates that the FDA approved robotic surgical system are limited in scope. Excluding the da Vinci®, no other robotic device can perform the array of unique, specialized requirements needed by VHA as compared to the da Vinci® Surgical Robot.

Manufacturer	**Device Name**	**Procedures FDA-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, thoracoscopically assisted cardiotomy procedures, and ear, nose & throat procedures.
TransEnterix	Senhance®	Laparoscopic colorectal and laparoscopic gynecological surgeries
Titan Medical	SPORT®	NOT FDA APPROVED AT THIS TIME

Currently, the DoD is the largest single buyer of the da Vinci® surgical system. The DoD procures these systems by a fixed priced financial arrangement with Intuitive Surgical, Inc., based upon catalog pricing. The VA will mimic this financial arrangement and has likewise used and relied upon the published catalog pricing as offered by Intuitive Surgical, Inc.

9. Other Facts: No other facts are applicable to this justification for other than full and open competition.

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: Daniel R. King

Title: Program Manager

Date: Daniel R King 1439669 Digitally signed by Daniel R King 1439669 Date: 2019.03.15 13:28:52 -04'00'

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 the comparison of commercial and government pricing.

Name: Zachary Wilcox

Title: Contracting Officer

Date: Zachary W. Wilcox 519033 Digitally signed by Zachary W. Wilcox 519033 Date: 2019.03.15 13:18:11 -04'00'

Signature:

12. Procuring Contracting Officer Certification:

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

Name: Zachary Wilcox

Title: Contracting Officer

Date: Zachary W. Wilcox 519033 Digitally signed by Zachary W. Wilcox 519033 Date: 2019.03.15 13:18:39 -04'00'

Signature:

13. Legal Sufficiency Certification:

I have reviewed this justification and find it adequate to support a limited source award and deem it legally sufficient.

Name: Vanessa Calabrese

Title: Legal Counsel

Date: Vanessa L Calabrese 393642 Digitally signed by Vanessa L Calabrese 393642 Date: 2019.03.15 13:48:27 -04'00'

Signature:

Approval

In my role as **Head of the Contracting Activity**, based on the forgoing justification, I hereby approve the acquisition of the 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: 7/24/19 Signature:

Thomas J. Loney
Head of Contract Activity

Approval

In my role as Senior Procurement Executive, based on the forgoing justification, I hereby approve the acquisition for 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: 24 JUL 19 Signature:

Dr. Angela Billups
Senior Procurement Executive
Office of Acquisition and Logistics (OAL)