[redacted]

CLASS LIMITED SOURCE JUSTIFICATION (LSJ)
DA VINCI SURGICAL SYSTEMS
SDV Medical Electronic Catalog (ECAT) Contract SPE2D1-25-D-0006

1. Defense Logistics Agency (DLA) Troop Support, Medical Supply Chain, Capital Equipment Division, is the contracting activity.

2. The action submitted for approval is a class LSJ for the placement of sole source delivery orders for the da Vinci robotic surgical systems, instruments, related accessories, upgrades, and maintenance services under the SDV Office Systems LLC d/b/a SDV Medical ECAT contract SPE2D1-25-D-0006 for the period commencing with the approval of this class LSJ through contract expiration. Intuitive Surgical, contracted through SDV Medical, is the Original Equipment Manufacturer (OEM). SDV Medical is the exclusive authorized supplier to the Department of Defense (DoD), Veterans Administration (VA), and other Federal Government customers for Intuitive Surgical Inc da Vinci robotic surgical systems, instruments, related accessories, upgrades, and maintenance services.

3. The acquisitions are for the purchase of the following surgical systems:

a) The DoD, Veterans Administration (VA), and other Federal Government customers have ongoing requirements for da Vinci robotic surgical systems, instruments, related accessories, upgrades, and maintenance services.

b) The total maximum dollar value of SDV Medical's ECAT contract is $360 Million. This contract is for a five (5) year period and no option period. The forecasted dollar value of the sole source delivery orders to be placed under the referenced five (5) year contract for da Vinci robotic surgical systems, instrument, related accessories, upgrades and maintenance services is [redacted]. Although the estimated sales are less than the maximum contract dollar value, the subject LSJ is not limited by the estimated sales.

4. The authority waiving the competition requirements is FAR 8.405-6(b)(1), only one source is capable of providing the supplies required at the level of quality required because the supplies are unique or highly specialized. Use of this authority is necessary because the da Vinci surgical system is the only robotic surgical system that meets the minimum requirements of DoD and various Government customers.

The minimum requirements of the US Government are as follows: A singular robot-assisted surgical system that shall have the U.S. Food and Drug Administration (FDA) clearance to perform all the following surgical procedures:

[redacted]

- Urological surgical procedures

[redacted]

[redacted]

- General laparoscopic surgical procedures
- Gynecologic laparoscopic surgical procedures
- General thoracoscopic surgical procedures
- Thoracoscopically assisted cardiotomy procedures

This class LSJ pertains to robotic surgical systems requirements including all the aforementioned procedures. Robotic surgical systems specializing in procedures outside the scope of these procedures are out of scope of this class LSJ.

A consolidated, single-source solution is required for the identified procedures to optimize patient outcomes by minimizing operational overhead. By reducing the need for multiple independent systems, this approach minimizes training complexity, decreases maintenance and repair overhead, lowers power and facility resource consumption, and conserves physical space in clinical environments. These efficiencies result in a reduced cost of ownership. Additionally, a single solution reduces system variability which contributes to improved procedural consistency, better patient outcomes, and shorter recovery time allows the war fighter to be back to full duty status.

Intuitive Surgical, contracted through SDV Medical, is the Original Equipment Manufacturer (OEM). SDV Medical is the only vendor authorized to perform the maintenance services on its da Vinci surgical systems. The da Vinci systems include proprietary hardware and software. The software elements run the complex algorithms required to perform the successful operation of the system. The hardware and software function together and were evaluated to be an approved system by the FDA. Proprietary clinical software used in da Vinci robotic surgical systems require licenses that only the OEM can provide. Upgrades to the proprietary system software can only be performed by Intuitive Surgical.

The da Vinci surgical systems manufactured by Intuitive Surgical and supplied by SDV Medical are the only robotic surgical systems that meet the Government's minimum requirements. SDV Medical is the exclusive authorized supplier to the DoD for Intuitive Surgical's da Vinci robotic surgical systems, instruments, related accessories, upgrades, and maintenance services. SDV Medical will contract with Intuitive Surgical to provide the necessary equipment, services, and training.

5. The Contracting Officer has determined the contract prices fair and reasonable based on a favorable comparison to VA pricing on their recently awarded Long Term Contract # 36C10G25D0013 awarded on 01/07/2025. Prices are also in line with the manufacturer's commercial invoices, and previous (expired) Intuitive contract SPE2D1-20-D-7005. In addition, a determination has been made by the contracting officer that the sole source orders to be placed under SDV Medical's ECAT contract represent the best value to the Government and will result in the lowest overall cost that meets the Government's minimum requirements (considering price, special features, and administrative cost) consistent with FAR 8.404(d).

6. Market research was conducted by Defense Health Agency representatives and validated by DLA Troop Support in June 2025 to ascertain if any other manufacturers can meet the Government's minimum needs for robotic surgical systems. Data was obtained using internet searches, consulting with the surgical subject matter experts, and ECAT system searches.

[redacted]

[redacted]

The listed requirements need to be accomplished by a single solution. Potential solutions were identified and assessed.

Six (6) alternate vendors were identified as possible solutions to meet the government's requirements: [redacted] The vendor's product offerings were reviewed for adherence to the minimum requirements. An overview of these offerings is captured below:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

[redacted]

[redacted]

Based on the market research performed, Intuitive Surgical is the only vendor who can provide a robotic surgical solution, instruments, related accessories, upgrades, and maintenance services that meet the Government's minimum requirements. SDV Medical is the only authorized distributor that offers Intuitive Surgical equipment.

7. In the event the FDA approves a robotic surgical system from another manufacturer with capabilities that meets the minimum requirements during the effective period of this class LSJ, this LSJ will become void and subsequent orders for robotic surgical systems will be competed between FDA-approved sources. This class LSJ is specific to SDV Medical as they are the only authorized distributor to the US Government that offers Intuitive Surgical equipment. In the event a second distributor could offer the items under the program, this class LSJ will become void and a new LSJ permitting competition among all dealers offering the Intuitive Surgical da Vinci robotic surgical system will be required.

8. DLA Troop Support will attempt to locate other acceptable sources for future routine requirements as they arise; however, any new item would be required to meet the minimum requirements of the Government.

9. As the Contracting Officer, I hereby certify that this addendum is accurate and complete to the best of my knowledge and belief.

[redacted]

Date

ANTHONY GIUNTA
Contracting Officer

I hereby certify that the requirements which form the basis of this justification are accurate, that these supplies meet the Government's needs in accordance with applicable specifications and that this justification is accurate and complete to the best of my knowledge and belief.

[redacted]

Date

[redacted]
Biomedical Engineer

[redacted]

[redacted]

Class LSJ- DA VINCI SURGICAL SYSTEMS- SDV Medical ECAT Contract SPE2D1-25-D-0006

I have reviewed and hereby approve this justification.

BEEBE.MATTHEW.R[redacted] Digitally signed by BEEBE.MATTHEW.RICHARD[redacted] Date: 2025.09.15 12:39:42 -04'00'

Date

MATTHEW R. BEEBE
Senior Procurement Executive

[redacted]