

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>\$150K)**

Acquisition Plan Action ID:

541-18-2-250-0151/VA250-18-AP-5353

1. Contracting Activity: Department of Veterans Affairs,
VISN 10,
Network Contracting Office 10
Northeast Ohio VA Medical Center

2. Description of Supplies/Services Required to Meet the Agency's Needs:

Due to the change in the Manufacturer's Indications for Use (IFU) for Intuitive Surgical Davinci XI Robot instrumentation, the Manufacturer now requires a set performance (48 Watts/Gallon or greater), Frequency (38kHz or greater) and Bath Size (large enough to fully submerge devices with at least 1-inch clearance around all ultrasonic bath edges.) Due to VHA Directive 1116 (2) SPS must follow the complete Manufacturer's IFU for the proper cleaning, decontamination, and sterilization of all Critical and Semi-Critical RME.

The equipment being purchased must also allow for the automated flushing of Cannulated Surgical Instruments and Davinci XI Endowrists/accessories.

The equipment being purchased must be able to process a minimum of 20 cannulated instruments per cycle.

Equipment must be able to process a minimum of 70 lbs. of surgical instruments per cycle.

Equipment must allow for fresh water to be used in every phase of the cycle and is then automatically drained. This prohibits the same water from being utilized.

CLEANSTART SURGICAL CS-0040-000	SPRINT SONIC IRRIGATOR WASHER DISINFECTOR	3
CLEANSTART SURGICAL CS-10000-000	INSTRUMENT CLAMP CONNECTORS (12 PER PACK)	2
CLEANSTART SURGICAL CS-1002-000	LUER LOCK CONNECTORS (12 PER PACK)	2
CLEANSTART SURGICAL CS-1003-000	XI CONNECTORS (12 PER PACK)	2

3. Statutory Authority Permitting Other than Full and Open Competition:

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for Ultrasonic Cleaners in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.

4. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

CleanStart Surgical (Skytron) currently meets the requirements for Davinci Instrumentation under the current Manufacturer's Indications for Use.

CleanStart Surgical currently meets the requirements for automated flushing of Davinci and cannulated instruments.

CleanStart Surgical currently meets the requirements for processing at least 20 cannulated instruments.

CleanStart Surgical is the only vendor that meets the requirements for processing at least 70 lbs. of instruments per cycle. This is required for SPS to increase work flow and increase processing of an estimated 6.5 million instruments per year.

CleanStart Surgical is the only vendor that meets the requirements of having fresh water used in every phase of the cycle and is then automatically drained. This practice prohibits the same water being utilized multiple time which can leave bioburden on instruments.

5. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

VetBiz, NAC, FSS, GSA ADVANTAGE, and GOOGLE were used to search for equipment to meet the needs of this requirement. The Sterile Processing Service also utilized testing, literature, and expert experience to find ultrasonic machines that had the potential to meet the needs of SPS. Similar equipment to the recommended equipment was found, however, that equipment did not meet the needs of the government. Only the CleanStart Surgical SPRINT SONIC IRRIGATOR WASHER DISINFECTOR can meet the requirements per the SOW and meet Form, Fit, and Function requirements including the Intuitive Surgical Davinci XI Robot instrumentation IFU and the VHA Directive 1116 (2).

6. Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:

Pricing is determined to be fair and reasonable based on previous similar acquisitions within the Department of Veterans Affairs, as well as market research pricing and the IGE.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:

The using service conducted market research by querying the hospital's technical experts, the operators using the requested equipment, and searching the internet. Contracting used the internet to search the VetBiz database, NAC search tool, the GSA search tool, FPDS-NG, FBO, and finally utilized Google.

7. Any Other Facts Supporting the Use of Other than Full and Open Competition:

N/A

8. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

SKYTRON LLC	Alliant Enterprises, LLC (Verified SDVOSB) Alliant Healthcare Products
DUNS: 078375583 CAGE Code: 8J631	DUNS: 121170653 CAGE Code: 3Y2R6
5085 CORPORATE EXCHANGE BLVD SE	333 Bridge Street NW, Suite 1125
GRAND RAPIDS, MI, 49512-5515	Grand Rapids, MI, 49504-5367

9. 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:

The using service and contracting will continue to conduct market research to determine if new equipment becomes available to meet the needs of the government.

10. 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.

Shawn P. Huelsman
Assistant Chief, SPS
Northeast Ohio VA Medical Center

3-30-2018

Date

11. Approvals in accordance with the [VHAPM Part 806.3 OFOC SOP](#):

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

Christopher A. Callihan
Contracting Officer
Network Contracting Office 10 (Indiana, Ohio & Michigan)

- b. **One Level Above the Contracting Officer (Required over\$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

Connie McKay
Branch Chief –Supply Team #2
Network Contracting Office 10 (Indiana, Ohio & Michigan)