

DEPARTMENT OF VETERANS AFFAIRS
Brand Name Justification and Approval (J&A)
For
Sorin S5 Heart-Lung Perfusion System

Acquisition Plan Action ID: VA259-17-AP-8776

Contracting Activity:

Department of Veterans Affairs
Network Contracting Office 19 (NCO19)
6162 South Willow Drive, Suite 300
Greenwood Village, CO 80111

Organizational Activity:

Department of Veterans Affairs
Oklahoma City VA Health Care System
921 N.E. 13th Street
Oklahoma City, OK 73104

2237: 635-17-3-071-0123

1. **Nature and/or Description of the Action Being Processed:** This procurement will be for a new firm-fixed-priced order with LivaNova (dba. Sorin Group USA, Inc) for the purchase of Cardiac Perfusion Machines (CMPs), required for surgeries at the Oklahoma City VA Health Medical Center. The proposed action is to justify an open market, Brand Name only combined synopsis/solicitation, set aside for Service Disabled Veteran Owned Small Business on FedBizOpps (FBO).
2. **Description of Supplies/Services Required to Meet the Agency's Needs:** The Sorin's S5 is a fifth-generation modular heart-lung machine used in the operating room, the heart-lung machine is used primarily to provide blood flow and respiration for the patient while the heart is stopped. Surgeons are able to perform coronary artery bypass grafting (CABG), open-heart surgery for valve repair or repair of cardiac anomalies, and aortic aneurysm repairs, along with treatment of other cardiac-related diseases. The heart-lung machine provides the benefit of a motionless heart in an almost bloodless surgical field. Cardioplegia solution is delivered to the heart, resulting in cardiac arrest (heart stoppage). The heart-lung machine is invaluable during this time since the patient is unable to maintain blood flow to the lungs or the body. The intended procurement is for one (1) Sorin S5 Console, Pump Modules, Tubing, Control Desk, SCP Centrifugal Pumps and DMS Connections with an estimated value of _____ and delivery date of September 22nd, 2017.
3. **Statutory Authority Permitting Other than Full and Open Competition:** FAR13.5 Simplified Procedures for Certain Commercial Items: The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(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):** The requested S5 Heart/Lung machines are essential to be compatible with the existing supporting supplies and disposables which would make this a cost effective procurement. The unit has better integration with the existing system.

The current unit has full text messages for alarms and warding to better provide for safety of the patient. All safety warning and alarms are recorded chronologically on the system display. The S5 is designed to meet the diverse needs of today's hospital—and then keep pace with you as your needs change. SIII and SIII Encore™ system users can transfer their external devices such as data management system or SCP to the new S5 System. They easily connect to the S5 using an adapter cable. The S5's memory chips are located within the various modules instead of centrally in a CPU. This ensures that each component functions as designed, in real-time. In addition, each module is completely replaceable and interchangeable. Use of this system will contribute to reducing the operating costs and long-term costs of the VA.

5. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Internet research, phone calls, and email requests were sent to a variety of potential vendors,

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including Service Disabled Veteran-owned Small Business, to identify capable vendors with the results detailed below in section 8. Market research that included research of similar procurements on the Federal Procurement Data System (FPDS) resulted in extended efforts of research with local and national VA contracting offices.

6. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The Contracting Officer has determined that the anticipated cost to the Government will be fair and reasonable based on comparison of historical pricing offered by two contractors who meet the brand name requirements.
7. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** The Oklahoma City VA Health Care System in Oklahoma City, OK, is in need of a purchase of one (1) Sorin S5 Heart/Lung machine. The current Sorin S3 in use at the medical center is obsolete and has reached the end of its "life Cycle", and is no longer able to be repaired due to the company discontinuing servicing of these machines. The requested S5 Heart/Lung machines are essential to be compatible with the existing supporting supplies and disposables which would make this a cost effective procurement. The new CPMs must be compatible with the CareScape B850 Patient Monitoring System, as well as the existing supporting supplies and disposables.

The current outdated, equipment can no longer be safely supported and used for quality patient care. As a result, the current machines will be traded in and replaced with the Sorin S5 Heart-Lung system. The unit is a full featured system with cardiovascular-flow capability for both the roller and centrifugal pumps. This feature enables the Perfusionist to easily record all values and events of the heart-lung machine. The Data Management System allows for charting and data storage for all hospital operating rooms in one central database, thereby avoiding inconsistent data inventory and enabling data compilation for studies and analyses. In addition, The Sorin S5 Heart Lung machines are the same machines that the perfusionists use at the affiliate University. For patient safety, it is important that the perfusionist and surgeons use a machine that they are already familiar with and comfortable using.

Market research, which included a search of the Vendor Information Pages (VIP) database, FPDS, FedBizOpps and GSA Advantage, gave indication that the Rule of Two in accordance with (IAW) 38 U.S.C. 8127(d) would be met by soliciting Service Disabled Veteran-owned small business (SDVOSBs). IAW Public Law 109-461, Sec. 8127, The contracting officer has a reasonable expectation that two or more small business concerns owned and controlled by veterans can meet the requirements of the purchase request at a fair and reasonable price.

The CPM purchase requirements awarded by this contracting office for the VAMC Salt Lake City on March 23, 2017 elicited with two (2) authorized SDVOSB distributors responded with supporting evidence of their ability to meet the requirements of the Sorin S5 CPM systems. It has since been determined that this purchase must be competed on FedBizOpps as a Brand Name Only combined synopsis/solicitation, set aside for SDVOSBs.

There are two major companies that manufacture heart lung machines, Sorin and Terumo. The VA researched the Terumo Cardiovascular Inc. Heart-Lung machines and found that the production of Terumo Advanced Perfusion System was scaled back by shipping restrictions imposed on the vendor by FDA. Although Terumo has since satisfied its Consent Decree with the FDA and the restrictions have been lifted, it would be some time before this vendor would be able to supply its bypass unit. The Terumo customer support was contacted and confirmed that their perfusions systems are not available for distribution and could not provide any timeframe for if or when they would be available. Such delays in implementing new CPMs at the Oklahoma City VA Health Care System would result in serious injury, financial or other, to the Government.


8. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** If the medical center transitions from the existing S3 to the new S5 units, the facility does not have to change over, all of the supporting supplies and disposables since they are already approved and in use at the facility.

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

Veterans Healthcare Supply Solutions
13949 Alvarez Road Healthcare
Suite 300 Supply
Jacksonville, FL 32218

BLK Perfusion Services, LLC
10 E Hunt Ave
Flagstaff, AZ 86001

10. **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:** NCO19 acknowledges the importance of protecting the integrity of the procurement system and are committed to working in manner that promotes competition to the greatest extent practicable in order to compete requirements and overcome barriers to competition. NCO19 will work manner that promotes competition to greatest extent practicable to compete future requirements and overcome barriers to competition in future acquisitions. The VA has and will continue to meet with industry on a periodic basis for continued input and feedback on acquisition strategies. The Requesting Service will continue working with the Rocky Mountain Acquisition Center in conducting market research to identify opportunities to compete future requirements.
11. **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.

Cindy Miller 
Staff Assistant, Surgery Service
OKC VAHCS

Date

12. **Approvals in accordance with the VHAPM, Volume 6, Chapter VI: 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.

Sarilynn Thomas
NCO19 Supply I Branch Chief of Contracting
Network Contracting Office 19

Date

- b. **Director of Contracting /Designee (Required over\$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

Gary Arwood
NCO19 Division II Chief of Contracting
Network Contracting Office 19

Date