

**DEPARTMENT OF VETERANS AFFAIRS**

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

**Acquisition Plan Action ID:** VA260-17-AP-3805

**1. Contracting Activity:** Department of Veterans Affairs, VISN 20, *Portland Medical Center* (648)  
PR # 648-17-2-188-0024

**2. Nature and/or Description of the Action Being Processed:**

The Portland VA Medical Center is requesting the purchase of a heart & lung machine (perfusion) for the OR. This new machine must be Sorin brand name because it must be compatible and interoperable with current Sorin equipment. The estimated price is [REDACTED].

**FAR13.5 Simplified Procedures for Certain Commercial Items:** This procurement will be utilizing 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.

**3. Description of Supplies/Services Required to Meet the Agency's Needs:** The equipment required is a double roller Sorin S5 Heart Lung machine with CP5 System, with an estimated cost of [REDACTED]. Estimated delivery date to be prior to Sept 1, 2017.

**4. Statutory Authority Permitting Other than Full and Open Competition:** This procurement will be utilizing FAR 13 procedure and suitable full and open competition for **Brand Name only**. In accordance with FAR 13.501 use as authority for brand name justification.

- (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- ( ) (2) Unusual and Compelling Urgency per FAR 6.302-2;
- ( ) (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- ( ) (4) International Agreement per FAR 6.302-4
- ( ) (5) Authorized or Required by Statute FAR 6.302-5;
- ( ) (6) National Security per FAR 6.302-6;
- ( ) (7) Public Interest per FAR 6.302-7;

**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 needs of the Portland VA require the manufacturer Sorin and model S5 heart lung unit with double roller pump, tubing insert

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of 1/8 x 1/16, color coded knob set, Edwards Lifescience/Baxter Truwave cable, and 60-00-60 CP5 System 1 controller.

There are two Sorin S5 heart lung machines in use at the Portland VA. The new system required by the Portland VA must have modular interoperability with these existing machines and utilize the same consumables, and equipment manufactured by Sorin will be the only type that has such interoperability and ensure the availability of replacement modules in the event any equipment issue is encountered during a patient procedure. In addition, maintaining the same manufacturer and model of equipment eliminates the risk of use errors from an alternate equipment manufacturer's operations and consumables. (Each manufacturer has a unique set of consumables for their equipment.)

The new heart lung machine will be utilized in the new Hybrid OR suite. The procedures performed there will include complex cardiac procedures up to and including TAVR. TAVR (Transcatheter Aortic Valve Replacement) is a heart valve replacement surgery that requires heart lung equipment. Due to the complexity and risks of the procedure, back up modules and equipment would be required immediately in the event of any equipment issues. This further supports the need for a Sorin S5 unit as opposed to any other manufacturer's equipment.

If an alternate equipment manufacturer's equipment is purchased, there would be no backup. This is clinically unacceptable.

If a heart lung machine is purchased that is NOT a Sorin brand S5, extreme clinical risks would result.

- There would be no pump, control or other component backup or replacement available. Different manufacturers do not have interoperability. Therefore, if there is an equipment problem with the singular, non-Sorin, unit the entire equipment would be down. If this happens in the middle of a case, adverse patient outcomes would result. In this situation, the entire equipment system would need to be replaced. The loss of time could result in adverse patient outcomes.
- Changing out an entire heart lung machine from one manufacturer to another would require a complete change in consumables. A significant amount of blood loss would occur from the tubing change.
- The consumables for the alternate equipment would not be the same as the existing. This introduces the risk of error and confusion utilizing the correct consumable for the correct machine. This also would increase the costs to the facility having two sets of consumables for the same type of equipment.
- There would be differences in operation between the Sorin unit and non-Sorin unit. The operational mechanisms, GUI (Graphi User Interfaces), meters, operational menus, "knobology", etc. would be different. This further increases the risk of use error. Use error in these types of critical situations could easily result in patient death.

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

This procurement will be utilizing FAR 13 through FBO for full and open competition.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** In accordance with FAR 13.106-3 the pricing is fair and reasonable based on competitive quote from vendors and/or comparison of the proposed price with prices found reasonable on previous purchases.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Extensive market research was performed. A search was conducted on Vetbiz.gov using NAICS code 339112 – Surgical and Medical Instrument Manufacturing. The search revealed that there are 165 SDVOSB registered on vetbiz.gov. However, the result of an FBO RFI shows no small business manufacturer can reasonably be expected to provide a quote, only distributors. Therefore, a full and open solicitation with no set-aside will be issued based on the estimated value and therefore the applicability of the Non-Manufacturer Rule.

9. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Veterans Healthcare Supply Solutions has requested interest in this acquisition.

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:**

When the current Sorin equipment outlives its designed operational life, a procurement can be conducted that allows for quotes from alternative manufacturers.

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.

GORDON P  
HOSODA 583943

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07/27/2017

Gordon Hosoda  
Biomedical Chief  
Portland VA Medical Center

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.

Jacob P Jackson  
457690

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Date: 2017.07.27 13:09:27 -07'00'

7/27/2017

Jacob Jackson  
Contract Officer

Date

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NCO 20

- 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.

Sheryl A. Chesnutt  
1034886

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Sheryl Chesnutt  
Division 2 Branch Chief  
NCO 20

Date