

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, VISN 4, VA Pittsburgh Healthcare System 1010 Delafield Rd, Pittsburgh, PA 15215. The requesting office responsible for this Justification for Other than Full and Open Competition is the Surgical Specialty Service Line. The 2237 purchase request number is 646-12-4-228-0446.
2. **Nature and/or Description of the Action Being Processed:** This is a Justification for Other than Full and Open Competition to award a sole source contract to St Jude Medical Inc. The type of contract planned is a firm-fixed price contract.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:**  
VAPHS needs to purchase ten (10) St. Jude Medical Inc Epic Mitral Valves. The requirement is for 5 different valve sizes, two of each. The sizes are 25mm, 27mm, 29mm, 31mm, and 33mm. This is a highly-specialized, brand name specific item. St. Jude's mitral valve has a patented, proprietary anti-calcification treatment applied to it which improves long-term performance and valve durability and reduces calcification in four ways.
4. **Statutory Authority Permitting Other than Full and Open Competition:**  
  - (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 heart valves to be purchased are highly-specialized, brand name specific items. The St. Jude Epic E100 mitral valve contains a patented, proprietary anti-calcification treatment called the Linx AC which is designed to improve long-term performance and valve durability that significantly reduces calcification in four ways. It reduces free aldehydes, extracts lipids, minimizes uptake of cholesterol and stabilizes leaflet collagen. The triple composite design features three separate porcine leaflets matched to optimize leaflet coaptation and reduce stress. The Unique Pericardial Shield on outflow edge and the flex fit system provides stent deflection and maximizes visibility and access to the cuff. The mitral holder provides improved visibility and cuff access. The valve sizer and system tray have a click in handle and a sizer design that provides the optimum ability to determine the accurate size to

ensure proper functionality. The appropriate implantable devices required by Veterans are determined by a physician on a case-by-case basis and are deemed a medical necessity.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** There is a history of past procurements with this company by Prosthetics. An Intent to Sole Source was completed and published on FedBizOpps stating that St. Jude Medical was the only vendor and manufacturer of this patented, proprietary valve. No responses were received.
  
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The prices for these valves are less than similar-sized valves that have been purchased by this facility from other manufacturers.
  
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research in the form of an Intent to Sole Source being published to FEDBIZOPPS was completed, stating that this procurement was sole source because of the patented, proprietary anti-calcification treatment that is on the manufactured valves. No responses were received. Patients' lives are dependent on VAPHS having the necessary mitral valves in an emergency situation. The valves come in five different lengths, and the service line is required to have two units of each length. We will purchase the minimum quantity necessary for patient safety, which are ten (10) valves.
  
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** Currently the mitral valves that are owned by VHAPTH will expire on August 09, 2012. These valves are used in emergency situations when a patient is receiving a catheterization and it is determined that their mitral valve is regurgitating to the point of possible early morbidity. If emergency surgical intervention is not performed the patient has a lesser chance of survival. Therefore, it is imperative that valves be replaced and readily available if this situation should occur. Due to this situation with the valves expiring, it is imperative that this existing procurement be processed immediately so that the valves are received before August 09, 2012.
  
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** None
  
11. **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:** VAPHS will award a sole source contract to St Jude Medical Inc for the required mitral valves.

12. **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.

Joelen Peltier

Name: Joelen Peltier  
Title: Administrative Officer  
Facility: UD

7-26-12  
Date: 7-26-12

13. **Approvals in accordance with FAR 6.304**

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

KATHLEEN S.  
POLICICCHIO  
152712

Digitally signed by KATHLEEN S. POLICICCHIO  
152712  
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Name  
Title  
Facility

7-26-2012  
Date

b. **NCM/PCM (Required \$3K and above):** I certify the justification meets requirements for other than full and open competition.

John A. Pawlik for

Name  
Network Contract Manager  
VISN/PCA X

7/27/12  
Date

Title  
Facility