

DEPARTMENT OF VETERANS AFFAIRS
Justification and Approval
For
Other Than Full and Open Competition

1. Contracting Activity:

Department of Veterans Affairs
NCO 15 Network Contracting Office
3450 S 4th Street
Leavenworth, KS 66048

2237 purchase request number: 657-13-3-8543-0337

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

The proposed Brand Name procurement action is to award a firm fixed price purchase order for the procurement of an ILUMIEN PCI Optimization System with ten (10) Dragonfly catheter kits for the Cardiac Catheterization (Cath) and Electrophysiology (EP) lab at the Saint Louis VA Medical Center from a small business authorized to distribute St Jude Medical equipment.

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

The proposed action is to provide the capital equipment, delivery and installation of the ILUMIEN PCI Optimization System for the Cardiac Cath and EP lab at the Saint Louis VA Medical Center. This is a coronary imaging system that utilizes both fractional flow reserve (FFR) and optical coherence tomography (OCT) technologies in one platform. Ten (10) Dragonfly catheter kits will also be purchased. This is a new contract for a one-time purchase with a total estimated value of \$147,000.00.

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

- (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 ILUMIEN PCI Optimization System constitutes highly specialized equipment that is only available from one vendor, St. Jude Medical Corp.. The ILUMIEN system is the only system that combines FFR and optical coherence tomography (OCT) technologies in one platform. The combined system offers physicians advanced physiological and anatomical insight to improve the diagnosis and treatment of coronary artery disease. FFR measurements indicate the severity of blood flow blockages in the coronary arteries and allow physicians to better identify which specific lesion or lesions are responsible for a patient's cardiac ischemia. A landmark study known as FAME (Fractional Flow Reserve (FFR) vs. Angiography in Multivessel Evaluation) demonstrated that FFR measurements helped physicians determine the best course of treatment for individual patients and resulted in improved outcomes for those patients. OCT diagnostic imaging technology allows physicians to visualize and measure important vessel characteristics not visible or difficult to assess with older intracoronary imaging technologies such as fluoroscopy and intravascular ultrasound (IVUS) imaging. OCT utilizes near-infrared light to create images that provide 10 times the resolution of images created using imaging technology. Used together, FFR and OCT technologies are especially important in the assessment of stent placement. Physicians can identify, measure, and visualize vessel characteristics for stent planning. Following stent placement, the high-resolution images of OCT show precisely how the stent is holding the artery open and whether it is positioned correctly against the artery wall, optimizing treatment and follow-up strategies. This will potentially minimize the need for repeat percutaneous coronary revascularization procedures. St. Jude Medical Corp is the only firm in the USA capable of providing the coronary imaging equipment that combine FFR and OCT technologies in one platform.

Due to the highly specialized technology offered only in the ILUMIEN PCI Optimization System, a Brand Name restriction will be utilized in the procurement. The acquisition of this specialized equipment is essential to the Government's requirements, thereby precluding consideration of a product manufactured by another company. In this instance, St. Jude Medical is the only manufacturer capable of providing the equipment described in Section III above without the Veteran's Health Administration experiencing unacceptable delays in fulfilling its requirements.

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

Market research was conducted to identify potential sources. A sources sought notice was published on Fed Biz Opps on 7/26/13 for a Coronary Imaging System with FFR and OCT assessment capabilities. Ellen Rick, director of National Accounts for St. Jude Medical, responded by email stating that St. Jude is the sole manufacturer of equipment meeting the requirements. TL Services, an authorized small business supplier for St. Jude, also responded by email stating that St. Jude is the only manufacturer of the requested equipment.

Market research efforts fully outlined in Section 8 demonstrate that St. Jude Medical is the sole manufacturer of equipment that meets the Government's requirements. Additionally, the proposed action will be synopsisized on the Federal Business Opportunities Page in accordance with FAR 5.201.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:

This contractor will provide information (i.e. other than cost or pricing data), which will include commercial price lists and prices for similar or the same services provided to other customers, to assist the Contracting Officer in determining if the contractor's proposed price is fair and reasonable for the services to be provided. The Contracting Officer anticipates the cost of this procurement to be fair and reasonable.

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

In accordance with FAR 10.002, market research was conducted to identify sources for this supply requirement. Market Research included a search of GSA and VA Federal Supply Schedule contracts. No existing contracts for a coronary imaging system with FFR and OCT technologies were identified. A search of the Vetbiz database and a sources sought email sent to four vendors found under 'coronary imaging' returned no results. A sources sought notice posted to FBO, as detailed in paragraph 6, resulted in responses from St. Jude Medical and an authorized distributor, asserting St. Jude as the sole manufacturer of the requested equipment. An internet search for coronary OCT supported the determination that only St. Jude Medical has this type of equipment available in the United States.

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


N/A

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

See section 6 above.

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: N/A

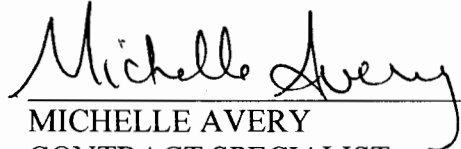
12. Requirements Certification: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.


Eric Miller, Supervisor, Cath Labs, StL VAMC

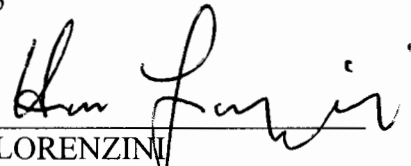
08-26-2013
Date

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.



MICHELLE AVERY
CONTRACT SPECIALIST
NCO 15

8/26/13
Date


HANS LORENZINI
CONTRACTING OFFICER
NCO 15

8-26-13
Date

b. NCM: I certify the justification meets requirements for other than full and open competition.


CHRISTINE L. SCENA
NETWORK CONTRACT MANAGER
NCO 15

8/26/13
Date