

DEPARTMENT OF VETERANS AFFAIRS

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

1. **Contracting Activity:** Department of Veterans Affairs, VISN 21, Network Contracting Office, VA Martinez Clinic, 150 Muir Road, Martinez, CA 94553-4668. This justification and approval is for other than full and open competition. 2237 number 612-15-1-291-0009.
2. **Nature and/or Description of the Action Being Processed:** This is for the rental of a coronary laser and lead removal system for the VA Northern California Health Care System, Surgical Services Department, at VA Mather, on a sole source, firm-fixed price basis.

FAR13.5 Test Program: This procurement is for the rental of a coronary laser and lead removal system, known as the Spectranetics CVX-300 excimer laser system, in accordance with FAR 13.5 Test Program 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 system to be purchased is called the Spectranetics CVX-300 Excimer Laser System, and it includes disposable catheters. This system is the only FDA-approved excimer laser system currently on the market, and it is used for the treatment of peripheral and coronary arterial disease. The Spectranetics CVX-300 Excimer Laser facilitates photo-ablation by way of a variety of Spectranetics catheters to remove binding arterial plaques. With this device, vascular surgeons will be able to remove intravascular tissue through photo-ablation; this is a minimally invasive treatment that may prevent seriously ill patients with critical limb ischemia from facing possible amputation. Total estimated value for this rental is \$336,000.00 (base year + option year 1.) Delivery shall be within 30 days ARO.
4. **Statutory Authority Permitting Other than Full and Open Competition:** 41 U.S.C. 1901 in accordance with 13.501(a)(ii):
 - (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;

FAR13.5 Test Program: The authority for applying the Commercial Test Program of FAR 13.5 is (Section 4202 of the Clinger-Cohen Act of 1996) and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).

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

Only One Responsible Source (FAR 6.302-1) – Spectranetics manufactures and markets the only excimer laser system and disposable catheters for the treatment of peripheral and coronary arterial disease. The Spectranetics CVX-300 Excimer Laser System facilitates photo-ablation by way of a variety of Spectranetics catheters to remove binding arterial plaques. With this device, vascular surgeons will be able to remove intravascular tissue through photo-ablation; this is a minimally invasive treatment that may prevent seriously ill patients with critical limb ischemia from facing possible amputation. Without this equipment, veterans would be required to go to hospitals outside the VA system to have these items removed. This would cost the Government significantly more than if it had the capability to perform these procedures in-house.

As such, Spectranetics Corporation is the only firm capable of providing the supplies and services described in Section 3 above without the Veteran's Health Administration experiencing substantial duplication of cost that could not be expected to be recovered through competition.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A brand name RFQ will be posted on FedBizOpps. Any responses received will be considered. However, only Spectranetics Corporation should be responding.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated cost will be considered fair and reasonable based on anticipation and verification that costs offered to the VA shall be in line with those extended to similar entities under similar circumstances.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** : FAR Part 10 directs that market research be conducted on each acquisition appropriate to the circumstances. The VANCHCS and VA Contracting Officer have conducted market research as required and have concluded that only one source is available to provide the equipment.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** : The current cost to rent the Spectranetics excimer laser system with disposable catheters is \$336,000.00 (which is \$168,000.00 for base year plus \$168,000.00 for one option year.) The harm to the Department of Veteran Affairs by not pursuing this acquisition would be the potential of higher costs to the Government. The VA would be required to refer Veterans to other hospitals outside the VA system to undergo laser coronary atherectomy and laser device lead removal, costing the VA significantly more than being able to conduct these same procedures in-house.

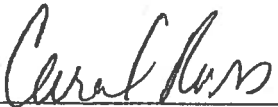
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**

Spectranetics Corporation
96 Talamine Court
Colorado Springs, CO 80907-5186
Attn: Jeff Corah 650-245-9010
Email jcorah@angioscore.com

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:** Future requirements for this equipment will be re-evaluated for the prospect of finding other manufacturers that can meet the same requirement as the Spectranetics Excimer Laser System. In the meantime, the VA is left with no other FDA-approved supplier to provide this equipment.

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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.

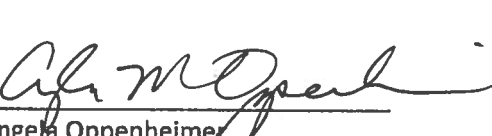


Carol Ross
Administrative Officer, Surgical Services
VISN 21, VA Mather

1-28-2015
Date

13. **Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP.**

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



Angela Oppenheimer
Contracting Officer, Supply Team II
NCO-21, VA Martinez

1/29/15
Date

- b. **Director of Contracting /Designee (Required \$150K and above):** I certify the justification meets requirements for other than full and open competition.

Patricia Benson
Branch Manager, Supply Team II
Director of Contracting Designee
NCO-21, VA McClellan

Date