Attachment 1: Request for SDVOSB/VOSB Sole Source Justification Format >SAT

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A) For Other Than Full and Open Competition (>SAT)

Acquisition Plan Action ID: VA256-18-AP-8217

- 1. <u>Contracting Activity</u>: Department of Veterans Affairs, NCO 16, Division II, Supply Team C, Overton Brooks VA Medical Center, Shreveport, 667. 2237# 667-18-3-132-0474
- **2.** <u>Nature and/or Description of the Action Being Processed</u>: Firm Fixed-Price Purchase Order resulting from soliciting a single source under FAR 13.5.
- **3.** <u>Description of Supplies/Services Required to Meet the Agency's Needs</u>: Turbo Elite Spectranetics Excimer Laser used to remove arterial blockage in chronically ill Veterans.

	M NO. DESCRIPTION	QTY UNIT		
STOCK NO.				
CVX-300	10 Excimer Laser System with a 12-month warranty.	1 EA		
410-152	1 TURBO-ELITE, 0.9mm Catheter (X-80, Cont. On) OTW	1 EA		
410-154	2 TURBO-ELITE, 0.9mm Catheter (X-80, Cont. On) RX	1 EA		
414-151	3 TURBO-ELITE, 1.4mm Catheter (80Hz, Cont On) OTW	1 EA		
414-159	4 TURBO-ELITE, 1.4mm Catheter (80Hz, Cont On) RX	1 EA		
417-152	5 TURBO-ELITE, 1.7mm Catheter (80Hz, Cont On) OTW	1 EA		
417-156	6 TURBO-ELITE, 1.7mm Catheter (80Hz, Cont On) RX	1 EA		
420-006	7 TURBO-ELITE, 2.0mm Catheter (80Hz, Cont On) OTW	1 EA		
420-159	8 TURBO-ELITE, 2.0mm Catheter (80Hz, Cont On) RX	1 EA		
420-050	9 TURBO-POWER, 2.0 mm , 150cm, OTW	1 EA		
410-152	11 TURBO-ELITE, 0.9 mmCatheter (X-80, Cont. On) OTW.	2 EA		
410-154	12 TURBO-ELITE,0.9mm Catheter(X-80,Cont.On)RX	2 EA		
414-151	13 TURBO-ELITE,1.4mm Catheter(80Hz-,Cont.On)OTW	2 EA		
414-159	14 TURBO-ELITE,1.4mm Catheter(80Hz-,Cont.On)RX	2 EA		
417-152	15 TURBO-ELITE,1.7mm Catheter(80Hz-,Cont.On)OTW	2 EA		
417-156	16 TURBO-ELITE,1.7mm Catheter(80Hz-,Cont.On)RX	2 EA		
420-006	17 TURBO-ELITE, 2.0mm Catheter (80Hz-, Cont. On) OTW	2 EA		
420-159	18 TURBO-ELITE, 2.0mm Catheter (80Hz-, Cont. On) RX	2 EA		
420-050	19 TURBO-POWER,2.0 mm,150cm,OTW	2 EA		

Estimated Total Price is less than \$400,000.00.

4. Statutory Authority Permitting Other than Full and Open Competition: 41 USC §3304(a)(5), 38 U.S. Code § 8127, as implemented by FAR 6.302-5 (Authorized or Required by Statute). COs may use the non-competitive (sole source) procedures authorized in VAAR 819.7007 or 819.7008 up to \$5,000,000. Check the specific VAAR clause used below:

(X) 819.7007 Sole source awards to a verified service-disabled veteran-owned small business; or

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- () 819.7008 Sole source awards to a verified veteran-owned small business
- 5. Demonstration that the Contractor's Unique Qualifications and/or Nature of the Acquisition
 Requires the Use of the Authority Cited Above (applicability of authority): According to the
 medical journal Interventional Cardiology Review, "The CVX-300 cardiovascular laser Excimer system
 (Spectranetics) ... is the only coronary laser-emitting device currently approved by the US Food and
 Drug Administration."

Market Research showed that only one Veteran-Owned Small Business has successfully accomplished the delivery and installation of this laser at three VA Medical Centers (New Orleans, Boston, Portland.) ERA Health, Ft Worth, TX is the exclusive SDVOSB distributor of the Spectranetics Excimer Laser.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable: A search of past awards for "excimer laser" was conducted. ERA Health was the only Veteran-Owned Small Business identified as having successfully obtained an award. They have successfully performed on three efforts of this type (New Orleans, 2017; Portland, 2016; Boston, 2014.) When contacted, their representative stated they are still the authorized distributor for the VA.

As a result of this research, we issued a Sources Sought – Sole Source Intent with this J&A attached to invite other Veteran-Owned sources who are capable to state their interest and demonstrate their capability. No other responses were received.

- **Reasonable:** During his Market Research, the customer obtained a quote from the manufacturer, Philips/Spectranetics to develop his IGCE. The pricing on previous orders with ERA Health compare favorably to this quote. A quote was obtained from ERA Health for the new laser for Shreveport. The pricing on this quote is determined Fair and Reasonable by the customer and the CO when compared to the IGCE developed for this effort.
- 8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted: This J&A was posted along with a Sources Sought Sole Source Inten to invite capable Veteran-Owned Small Businesses to express their interest and state their capability. No responses were received.
- 9. Any Other Facts Supporting the Use of Other than Full and Open Competition: ERA Health has met all the conditions required for a SDVOSB award. The order will be less than \$5M, the Justification will be made publicly available prior to award, their past performance on similar efforts supports their responsibility, and award can be made a Fair and Reasonable Price.
- 10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition: To Be Determined.
- 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: Because the Spectranetics Excimer Laser is the only FDA-approved device offering the capability to alleviate arterial blockage in chronically-ill Veterans, the market is dominated by one manufacturer.

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As new devices and techniques are developed and other suppliers enter the market, we will seek Small Business capability to satisfy requirements, with a strong focus on Veteran-Owned and Service-Disabled Veteran-Owned Small Businesses. Procuring from a SDVOSB firm for this procurement may lead to discovery of further competition on similar requirements where none was contemplated before.

12. <u>Requirements Certification</u>: 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.

Knitchell	7/17/19
Komeka Grigsby-Mitchell	Date
Program Support Assistant	
Overton Brooks VAMC	

- 13. Approvals in accordance with the VHAPM Part 806.3 OFOC SOP:
 - a. <u>Contracting Officer or Designee's Certification (required):</u> I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Paul G Filhiol 664375	Digitally signed by Paul G Filhiol 664375 Date: 2018.07.17 09:36:27 -05'00'				
PAUL FILHIOL	Date				
Contracting Officer					
NCO 16, Division II, Supply Team C SHR					

b. One Level Above the Contracting Officer (Required over the SAT but not exceeding \$700K): I certify the justification meets requirements for other than full and open competition.

Renata Ott 1604558	Renata Ott 1604558 2018.07.17 10:45:08 -05'00' 2018.011.20040
Renata Ott Branch Chief NCO 16, Division II, Supply Tear	Date n C ALX

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