

**DEPARTMENT OF VETERANS AFFAIRS**

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

**Acquisition Plan Action ID: 36C242-18-AP-3576**

1. **Contracting Activity:** Department of Veterans Affairs, VISN 02, VISN 2 Network Contracting Office; NY Harbor Healthcare System (NYHHCS), Manhattan Campus, 423 E. 23<sup>rd</sup> St., New York, NY 10010. Purchase request number: [REDACTED]

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

This is a request for a new, firm-fixed price contract to procure a BrainLab Cranial/Spine Navigation system. This system will be integrated with the newly purchased operating microscope, and will also have the capability of performing deep brain stimulation (stereotaxy). With the addition of the BrainLab Cranial/Spine Navigation system, surgeons will be able to continue to service brain/spine patients, as well as those requiring deep brain stimulation, resulting in significant savings and added convenience for patients. This system is required to support the facilities neurosurgical case load.

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

Brain Lab Cranial/Spine Navigation system, including platform software and license support, cranial and spinal accessories, Leica Microscope Integration (existing operating room microscope), and initial Navigation System disposables; [REDACTED]

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):**

There are only two Cranial/Spine Navigation systems currently on the market. Medtronic Stealth System and BrainLab's Cranial/Spine Navigation systems. BrainLab equipment is required because this brand of equipment is used exclusively by the Neurosurgery affiliate at NYU and Bellevue. All VA Surgeons, Attending and Resident rotate between NYU, Bellevue, and the VA as part of the program. All Neurosurgeons who will use the equipment are already trained and are using this

system at the other two hospitals. The neurosurgery and ENT residents have been trained using this equipment, therefore their familiarity with the equipment will enable them to provide the necessary patient care without a gap in training. This new instrument purchase must be consistent for staff familiarity, ease of use, and patient safety. It is imperative that the equipment be standardized whenever possible to ensure that set up, use, and reprocessing are conducted properly. This system will be integrated with the existing operating room Leica M530 OH6 microscope and will have the capability to also perform deep brain stimulation (stereotaxy).

The existing system at NYH is ten years old and has reached end of life. The older system has irregularly worked for the past two years and to avoid any incidents, NYHHCS has outsourced (VA Choice Program) some brain and neurological cases requiring deep brain stimulation (DBA).

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

A sources sought notice was posted to Federal Business Opportunities (FBO) on September 11, 2018. One response was received from the SDVOSB vendor listed in Section 10. Due to the Non-Manufacturer rule and the dollar amount of the IGCE, this procurement cannot be set-aside for any small businesses concerns.

The results of a search of the GSA eLibrary yielded forty-six (46) Federal Supply Schedule (FSS) holders under schedule 65 II A under the Special Item Number A-9 for "Scopes, Medical". None are authorized distributors of BrainLab, Inc.

A query of the VetBiz Vendor Information Pages (VIP) for BrainLab and the NACIS Code (339112) yielded no results. A search of VIP using the DUNS for Red One Medical Devices, LLC, showed that they are registered in VIP as an SDVOSB.

Market research conducted by the customer is as follows: NYHHCS reviewed several potential sources for Cranial/Spine Navigation systems. BrainLab Cranial/Spine Navigation systems is the only manufacturer that meets all the requirements needed for this Neurosurgical Program. Two vendors were able to provide the specific brand name equipment, BrainLab and their authorized SDVOSB distributor RedOne Medical.

**7. Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** Prior to award, the Contracting Officer will compare pricing against the IGCE and current market price lists to determine whether the offeror's price is fair and reasonable.

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

Market research was conducted through queries on the General Services Administration (GSA) eLibrary database, the US Department Veterans Affairs Office of Small & Disadvantaged Business Utilization Vendor Information Pages (VIP) of the VetBiz website, and the Small Business Administration Dynamic Small Business Search. A sources sought notice was posted to Federal Business Opportunities (FBO) on September 11, 2018.

VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP  
Attachment 2: Request for Sole Source Justification Format >SAT

Two vendors were able to provide the specific brand name equipment. BrainLab, Inc. and their SDVOSB authorized distributor Red One Medical. The product specifications from both quotes are identical.

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

Continuity and Standard of Care. The VA NYH Neurosurgical Program has rotating residents between NYU and Bellevue hospital who are already trained on the Brain Lab Cranial/Spine Navigation systems. This will allow the Neurosurgical Program to provide patient care without a gap in training and familiarity of use will reduce adverse patient outcomes.

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

BrainLab  
RedOne Medical

**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:** The Government will continue to conduct market research to ascertain if there are changes in the market place that would enable future actions to be competed.

**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.

July 8<sup>th</sup>, 2018

[Redacted Signature]

13. Approvals in accordance with the [VHAPM Part 806.3 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.

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

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