

**DEPARTMENT OF VETERANS AFFAIRS**

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

**Acquisition Plan Action ID:** VA242-17-AP-10877

**Transaction Number:** 630-18-1-4947-0002

1. **Contracting Activity:** Department of Veterans Affairs, Veterans Health Administration, Network Contracting Office (NCO 2), Bronx, New York.

2. **Nature and/or Description of the Action Being Processed:** The J&A is to support the award of a contract on a sole source basis with Mobius Bionics Inc. for service and repair of upper prosthetic limbs, LUKE Arms, prescribed by a physician as the optimum method of treatment for a specific patient treated under the care of a Veterans Administration Hospital.

**FAR13.5 Simplified Procedures for Certain Commercial Items:** This procurement is for an externally powered "Luke Arm" in accordance with FAR 13.5 Simplified Procedures 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 services required are for the repair and servicing of eight available LUKE arms (arms were obtained through Defense Advanced Research Projects Agency) that will be prescribed to eligible beneficiaries. This service contract includes the LUKE arm prosthesis as a whole, including all internal and external componentry (including but not limited to fixtures, motors, bearings, and electronics) with the exception of the specific items considered replacement (non-repairable/consumable) components. Total estimated cost including base year plus one option is \$240,000.00.

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):** Prosthetic limb components are specified by the clinical team to meet the unique and comprehensive needs of each Veteran with

amputation. The specific product described above has been determined by the clinical team to be the best device to treat the Veteran patient's medical condition and functional limitations. The Luke arm is solely made and distributed by Mobius Bionics Inc and no comparable device exists on the market. Substituting a prosthetic limb component with other than that specifically prescribed would be detrimental to the treatment of the Veteran. Full and open competition for the above described prosthetic limb component negates the clinician's subject matter expertise as related to the medical treatment for the individual Veteran. In this case the by-name device(s) is/are the specific prescription and method of treatment for the Veteran-patient.

As the needs of each patient are unique to each Veteran being treated, it is the attending physician's authority to prescribe the method of treatment to best satisfy the medical condition of his/her patient. Denial of the ability of physicians to prescribe specific treatments to their patients would adversely affect VA facilities to render proper patient centered care.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** This J&A covers a vendor, Mobius Bionics Inc, who will specifically provide prosthetic appliances or services and has been specifically prescribed by an attending physician to best treat the Veteran patient. No further action to complete these requirements will be accomplished, as it is the authority of the physician to judge the level of treatment necessary to satisfy the care needs of his/her patient. Additionally, the item and technology required to service the item, are proprietary to the contractor, so they are the only ones qualified to provide the service.
7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** The fair and reasonableness of the cost/price will be based on the analysis of the contractor's quote, including back up information supporting the cost/price with prior similar contracts or purchase orders in accordance with FAR 13.106-3. It is anticipated that this analysis will be conducted using experienced technical representatives, contract specialists, and field pricing support.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research has discovered that Physician's treatment methodology is based largely upon the judgement of what is best for each individual patient. There are multiple companies that provide Orthotic and Prosthetic Appliances with various differences between each product or service. Those differences are weighed by the Physician and a decision is made on the most effective manner of treatment for each Veteran patient's needs. Further market research has also determined that these appliances or services have been developed with funding from both the Department of Defense and the Department of Veterans Affairs and are now readily available. This device is the only one of it's kind commercially available in the United States, and the only source is the contractor Mobius Bionics Inc.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** VAAR 806.302-5(b)(1) allows an exception to full and open competition for prosthetic appliances in accordance with 38 U.S.C. § 8123. As previously mentioned, the right of a Physician to make a judgement call on the most advantageous method of treatment is the core reason for utilizing other than full and open competition procedures. Full and open competition would open the way for outside sources (i.e.

VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP  
Attachment 2: Request for Sole Source Justification Format >\$150K

contracting, providers, etc.) to exercise professional judgement and circumvent a Physician's treatment methodology. This is part of a custom device specifically made to replace a patient's missing hand and/or arm.

**10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Department of Veterans Affairs Amputation System of Care leadership

**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:** Based on the medical determination above, no further actions are contemplated. For the reasons set forth in paragraphs 5 & 9, the Veteran health Administration has no plans at this time to compete further contracts or purchase orders for the types of supplies/services covered by this J&A. The Veterans Health Administration will assess whether competition of future requirements are feasible based upon regular analysis of supplies/services being purchased and market conditions. Again, these are part of a custom prosthesis specifically made to replace this specific patient's missing upper limb.

**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.

**RICHARD L  
DIAZ 145923**  
Richard Diaz  
Name  
Title: Chief VISN2 Downstate PSAS  
Facility: VA New York Harbor Healthcare System

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September 21, 2017  
Date

**13. Approvals in accordance with the VHAPM Part 806.3 OFOC SOP:** *This part if filled out by Contracting Staff as part of the Justification*

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.

**LAWRENCE G  
UNGER 611402**  
Lawrence Unger  
Branch Chief, NCO 2  
Network Contracting Office, NCO2

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VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP  
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- b. **One Level Above the Contracting Officer (Required over\$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

HOPE L.  
FREEMAN  
126108

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NCO 2 Director of Contracting or Designee

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Date