

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval For

Other than Full and Open Competition

1. Contracting Activity: The U.S. Department of Veterans Affairs, Network Contracting Activity 18, located at 3601 S. 6th Ave, Tucson, AZ 85723, proposes to enter into a firm-fixed purchase order on the basis of justification for other than full and open competition for the Southern Arizona VA Health Care System (SAVAHCS). The Purchase request number is 678-12-2-5914-0643
2. Nature and/or Description of the Action Being Requested: This is a new procurement and the contract contemplated will be firm-fixed price purchase order to iWalk of 4 Crosby Dr., Bedford, MA 01730.
3. Description of Supplies/Services Required to Meet the Agency's Needs: This requirement is to provide SAVAHCS with a power foot, iWalk BIOM bionic lower leg system with power plantar flexion that stimulates the action of the anatomical ankle, Achilles tendon and calf muscles. The cost of this unit is \$42,000.00 each. The prosthetic power foot helps reduce metabolic demand by up the 50% reduces forces on the contra-lateral foot, and increases range of motion on the prosthetic sides. This method of ambulation is unknown in the field prior to the development and presentation of this foot. The use of this power foot will significantly improve the function and quality of life of our amputee veterans/veteran patient population. Due to the power characteristics of this component there are significant reductions in trauma and stress to the amputee during normal ambulation. Delay in award will put the veteran amputee's overall health at risk for falls and contra-lateral trauma due to imbalances associated with a non-powered foot.
4. Statutory Authority Permitting Other than Full and Open Competition: 41 USC §253(c)(2), as implemented by FAR 6.302-1.
 - (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 per 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): iWalk of 4 Crosby Dr., Bedford, MA 01730, is the unique manufacturer of the Bionic Foot required

at the SAVAHCS. Market research done has not identified any other company that is able to provide a similar prosthetic device. There is but one power foot on the market, no other manufacturer has developed this technology. This product is significant as it relates to our veteran diabetic patients due to the noted stresses relegated to the contra-lateral side. It is well documented that within three years of the initial amputation of one side that a second amputation will occur on the remaining sound side, and within years following that, death. Research demonstrates that due to the lack of true anatomical mimicry of existing prosthetic feet excessive forces noted during ambulation is transferred to the remaining foot. In addition, due to the advanced age of these veterans/amputees and likely osteopenic bone conditions, falls are a significant concern. Patient's are at risk for falls thus potentially generating additional medical intervention and costs. Delay in award will put the veteran amputee's overall health at risk for falls and contra-lateral trauma due to imbalances associated with a non powered foot.


6. Description of efforts made to ensure that offers are solicited from as many potential sources as deemed practicable: No potential sources were found after searching GSA Advantage. An internet search was conducted with negative results of similar technology. A call was placed to the manufacturer, as well as industry research completed and no other manufacturers offer similar function with their products.

Future acquisition strategy and efforts: A Prosthetics team is being developed by the VISN 18 headquarters, in order to establish, find and solicit contracts and consignment agreements from several medical manufacturers.

7. Determination by the Contracting Officer that the anticipated cost to the Government will be Fair and Reasonable: The anticipated dollar value for this contract action is \$42,000. The Bionic foot has been determined to be commercial in accordance with FAR 2.101; cost or pricing data will not be required. Pricing techniques as are described in FAR 15.404-1(b)(2), will be used to establish price fairness and reasonableness. The Contracting Officer determines that the anticipated price will be fair and reasonable based on historical price analysis of similar technology. Market research and analysis of the contract in place for similar items provide evidence of fair and reasonable pricing. Market research indicates no other companies could meet the requirement as needed.
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. A search for other potential suppliers was completed on GSA Advantage. The results of market research indicated no potential sources that can provide the iWalk Biom Bionic foot required for our veteran amputee patients at SAVAHCS. CCR, NAICS, and VetBiz did not result in the identification of any potential manufacturers/suppliers of similar technology.
9. Any other facts supporting the use of Other than Full and Open Competition: Elderly veteran amputee patients with diabetes are at risk for co-morbid issues such as obesity, osteopenic bone deficits secondary to lack of mobility/activities and contra-lateral limb jeopardy. Decreased mobility/activities promote decreases in overall health and quality

of life. In an effort to reduce secondary amputations this veteran population needs to be as active as physically possible. This effort will reduce secondary medical issues and maintain veterans' mobility thus promoting good healthy diabetic patients.

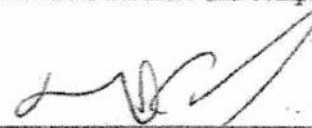
10. Listing of sources that expressed, in writing, an interest in the acquisition: See section 6 above.
11. A statement of the actions, if any, the agency may take to remove or overcome any barriers to competition before making subsequent acquisitions for the supplies or services required: The agency clinical staff will continue to evaluate new technology, specifically myoelectric terminal devices, to determine when a competitor's system can manage the same range of functional capabilities through this evolving technology.
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


David L. Davis, CEO
Supervisor, Orthotic & Prosthetic Lab
Southern Arizona VA Health Care System

1/19/12
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.


Contracting Officer
Tucson AZ Contracting Office VISN 18

20 FEB 2012
Date

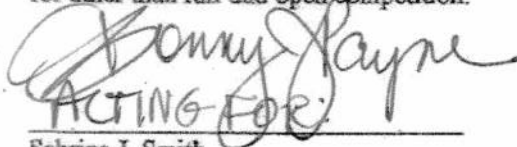
- b. VISN/PCA OA (Required \$3K and above): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.


→ VISN18 QA/COMPLIANCE PROCUREMENT ANALYST
Paulette Pereira
Procurement Analyst
VISN 18



Date

- c. NCM/PCM (Required \$3K and above): I certify justification meets requirements for other than full and open competition.


ACTING FOR:

Sabrina J. Smith
Network Contract Manager
VISN 18

3/14/12
Date