

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

VA-241-12-R-0080

1. Contracting Activity: Department of Veterans Affairs, Network Contracting Office 1 (New England), Providence VA Medical Center (241/650/90C) Purchase request: 650-12-1-866-0012.
2. Nature and/or Description of the Action Being Processed: The contract action to be approved is the sole-source award of an Indefinite Delivery contract (IDC) for full logistical maintenance, support and training for robotic prosthetic arm systems for research. This is a new VA contract, solicitation number VA-241-12-R-0080. The proposed contractor is DEKA Integrated Solutions Corp (DISC), 340 Commercial St, Manchester, NH 03101 (DUNS: 794762349, CAGE: 38YT6).
3. Description of Supplies/Services Required to Meet the Agency's Needs: The contractor will provide logistical service and support to the VA Research/Education activity (151), VAMC Providence for the prosthetic arms purchased under contract VA241-P-2466 and to legacy Gen 2 and Gen 3 arm systems. The training and technical support will be used for Institutional Review Board (IRB) approved research projects. The contractor shall provide full engineering support for reconfiguration of the arms, and incidental or minor technical support and repair. The estimated value of the contract is approximately \$543,000 for the first year and approximately \$3,200,000 for the total contract duration. A five year Indefinite Delivery Contract (IDC) is under consideration.
4. Statutory Authority Permitting Other than Full and Open Competition: 38 USC § 8123 and 41 USC § 253(c)(5), as implemented by VAAR 806.302-5(b) and FAR 6.302-5 Authorized or required by statute.
 - () (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;
 - (x) (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.

The text of the enabling statute and regulation are set forth as follows:

Procurement of Prosthetic Appliances The Secretary may procure prosthetic appliances and necessary services required in the fitting, supplying, and training and

use of prosthetic appliances by purchase, manufacture, contract, or in such other manner as the Secretary may determine to be proper, *without regard to any other provision of law.* 38 USC § 8123

Authorized or required by statute. Various sections of title 38 U.S.C. authorize the Secretary to enter into certain contracts and certain types of contracts without regard to any other provisions of law. When the contracting officer enters into a contract without providing full and open competition for any of the following items or services, the contracting officer must cite 41 U.S.C. 253(c)(5) and the following authorities:

(1) *For contracts for orthopedic and prosthetic appliances and related services including research, cite 38 U.S.C. 8123. (38 U.S.C. 8123) VAAR 806.302-5(b)*

This acquisition is within the ambit of the referenced statute and regulation; therefore, the VA is exempt from competing this acquisition for prosthetics research services.

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

The Department of Veterans Affairs invokes its authority 38 USC § 8123 for this advanced prosthesis system. In addition, the following facts and history support this acquisition.

On July 24, 2004, representatives from VA and Department of Defense (DOD) testified before the House Committee on Veterans' Affairs on the need for more collaboration between VA and DOD in both research and care for service members who had lost one or more limbs. Representatives from Defense Advanced Research Projects Agency (DARPA) stated that they were about to undertake a new high-risk research project to drastically improve the quality of life for individuals who had lost one or more limbs. DARPA envisioned future advanced artificial arms that would allow the ability to type on a keyboard or play a musical instrument, and allow the user to actually feel precisely whatever the artificial arm might be touching. After developing such arms, DARPA would seek transition partners such as VA and specialized DOD facilities to perform the critical and final stages of design and engineering, as well as clinical development and testing. VA representatives noted the Office of Research and Development's (ORD) long history of funding innovative and groundbreaking research projects in prosthetics and orthotics. The integrated VA research and clinical care system would be able to serve as an ideal incubator for these DARPA technologies, to help move these advanced prosthetic arms into routine daily use by our veterans. VA would thus be ideally positioned to serve as one of DARPA's transition partners when the results of the DARPA research would be ready for clinical research and testing.

In 2005 DARPA announced its "Revolutionizing Prosthetics" Program and funded the development of the advanced prosthetic arms in successive engineering generations (Gen 1, Gen 2 and Gen 3) via contracts with DEKA Integrated Solutions Corporation (DISC). In 2008, the VA, through a Memorandum of Understanding with DARPA and a Co-operative Research and Development Agreement (CRADA) dated June 25, 2008 with DISC, initiated optimization studies of the Gen 2 advanced prosthetic device. The final result of these studies, and the DARPA funding was the development of the Gen 3 advanced prosthetic arm. The Gen 3 DEKA Arm incorporates major technological advances in hardware, socket design, innovative control features and software that together enable enhanced functionality that promises to surpass any currently available prosthetic device.

The next step in clinical testing of the Gen 3 Arm is a long-term take home study of the arm in which Veterans will be trained to use the Arm, and then will take it home for several months of use. The VA, led

by Dr. Linda Resnik, will initiate this take home study in fiscal year 2012. Technical support is required to configure the Gen 3 Arm for study subjects, and repair the devices as needed. Furthermore, VA study staff requires regular technical advice and training to insure that they are maximizing the functionality of the device.

DISC is uniquely qualified to supply the required service and support of the Gen 3 prosthetic arm systems to the VA and support the associated studies based upon the following:

a. The Gen 3 advanced prosthetic arm was developed under contract with DARPA and is a pre-commercial prototype. DISC has the mechanical, electrical, biomedical and software engineering expertise to assemble, configure, troubleshoot and repair the Gen 3 arm. Furthermore, DISC staff has the expertise to train VA study staff in set-up and configuration of the robotic arms and use of the socket system.

b. Engineering support of the Gen 3 arm is not available from any other source at this time. DISC is the only source available to provide this technical support.

c. DISC engineers have worked with the research team at the Providence VA since 2008 to provide staff training, engineering and technical support for VA studies of the Gen 2 and Gen 3 advanced prosthetic Arm System. In 2008, the VA installed a Tandberg Edge Video Conferencing system on the DEKA premises that allows DISC to communicate with VA Study Staff within the VA firewall. Each of the VA study sites has a Tandberg videoconferencing system that allows them to transmit images of the device and zoom in to see particular parts and functions. This capability is critical for remote technical assistance. The VA Tandberg equipment will remain on DISC premises during the terms of this contract, facilitating communication and troubleshooting of technical issues.

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

A synopsis of this contract action was posted (12/2/2011) to FedBizOpps (FBO), the Government Point of Entry. To date, no responses have been received. Interested vendors and researchers may contact the contractor directly for subcontracting, supplier or collaborative opportunities.

Other actions: The VA Providence Principal Investigator, Unda Resnik, PhD, the Contracting Officer Technical Representative and the VACO Director of Deployment Health, Robert Jaeger, PhD, will continue to monitor and survey research developments in the field of advanced prostheses.

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 upon the following basis.

The contractor shall submit both a technical and a cost proposal for the labor categories proposed for the IDC. The cost proposal shall be compared to the Independent Government Estimate for cost realism purposes. Certified cost and pricing data will be requested to support the analysis. The contractor shall provide a breakdown of labor categories with rates and costs for the appropriate labor category (e.g. engineer, technician, test engineer, QA engineer/technician, field technician etc.) Indirect Costs: the contractor shall show its indirect rates and the basis to which they are applied. Other costs: the contractor shall be required to list other costs and categories, including, special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework. The Acquisition Team will

evaluate both the technical proposal and the cost proposal.

The IDC will have an overall contract ceiling and each task order issued under the IDC will also have a ceiling. In order to facilitate prospective negotiations for the level of effort for each task order, the Program Office will furnish an independent estimate that defines the expected level of effort for each task order. The contractor will be asked to propose their level of effort and disciplines for associated tasks so that a realistic ceiling for the order can be negotiated and achieved.

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

The VA Providence Principal Investigator, Linda Resnik, PhD and the Acting Director of Deployment Health, Robert Jaeger, PhD, continue to monitor, survey and inform VA ORD of research developments in the field of advanced prostheses.

DISC is providing robotic prosthetic arm and hand assemblies (VA contract VA241-P-2466). They are the only vendor available to provide service and support for this acquisition. No other vendors are capable of providing this service.

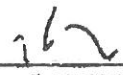
9. Any Other Facts Supporting the Use of Other than Full and Open Competition: None. There are no other vendors capable of this work.

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition: See paragraph 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 contract action is synopsized to the business portal, FedBizOpps (FBO). Interested vendors and collaborators may contact the contractor directly for opportunities relating to this acquisition. The VA will continue to monitor developments of the Johns Hopkins University Applied Physics Laboratory (APL) and other advanced robotic arms. The VA Rehabilitation, Research and Development (RR&D) office will continue its liaisons with researchers and scientific administrators at National Institute of Health (NIH), DARPA and the DoD Army Medical Commands. This Justification and Approval (J&A) will be posted to the Government Point of Entry, FBO.

(see attached signature page)

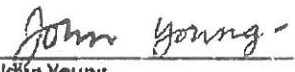
12. Requirements Certification: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.


Linda Resnik, PT, PhD
Research Health Scientist
Providence, RI VAMC 650/151

1/10/12
Date

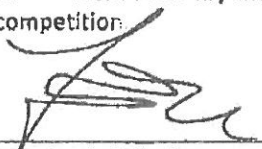
13 Approvals in accordance with FAR 6.304

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


John Young
Contracting Officer
Network Contracting Office 1 (NCO 1 - New England)

1/10/2012
Date

b. **NCM :** I certify the justification meets requirements for other than full and open competition.


Francis M. Callaghan
Network Contracts Manager
Network Contracting Office 1 (NCO 1 - New England)

1/11/2012
Date

c. **SAO East:** I certify the justification meets requirements for other than full and open competition.

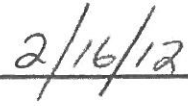

David M. Fitzgerald
Director
Service Area Office, East

6 Feb 12
Date

d. VA Review and Approval: I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.



Norbert S. Doyle
Chief Procurement and Logistics Officer
VHA Head of Contracting Activity (HCA)



Date