

**DEPARTMENT OF VETERANS AFFAIRS**  
**Justification and Approval**  
**For**  
**Other Than Full and Open Competition**

**1. Contracting Activity:** Department of Veterans Affairs, VISN 16, Little Rock, Arkansas.

**2. Nature and/or Description of the Action Being Processed:** The proposed contracting action is for a firm-fixed price purchase order for one (1) L-Dex U400 Complete Kit, to include the following: L-Dex U400 BIS Device, Lead Set, Alligator Clips, Test Cell, Software CD-ROM, Packet 60 ImpediMed Electrodes, Device Manual – Hard Copy, Software Manual – Hard Copy, Carry Case, 12 Month Warranty Coverage; and one (1) #292-DTE Electrodes. The purpose of this justification is to request sole source approval for a purchase order with ImpediMed, Inc., 5959 Cornerstone Court West, Suite 100, San Diego, CA 92121

**3. Description of Supplies/Services Required to Meet the Agency's Needs:** Physical Medicine Rehabilitation Service (PMRS) has a requirement for a device that uses electrical impedance to assess early fluid retention to assist in the diagnoses of lymphedema in the limbs, both arms and legs, as approved by the Food and Drug Administration (FDA) for this purpose. There is no other known method to objectively and accurately diagnose pre-clinical findings of lymphedema. ImpediMed's L-Dex U400 BIS device is the only known device on the market that evaluates post lumpectomy, post lymphectomy cancer patients in this manner. The estimated value of this requirement is \$30,300.00. The North American Industry Classification System (NAICS) number for this procurement is 339112 Surgical and Medical Instrument Manufacturing with a small business size standard of 500 employees. The Federal Supply Code (FSC) for this procurement is 6515 Medical and Surgical Instruments, Equipment and Supplies.

**4. Statutory Authority Permitting Other than Full and Open Competition:**

The justification rational is based on FAR 6.302-1 Only one responsible source and no other supplies or services will satisfy agency needs and authorized pursuant to 41 U.S.C. 253(c)(1).

**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 is no other known method to objectively and accurately diagnose pre-clinical findings of lymphedema that uses electrical impedance to assess early fluid retention to assist in the diagnoses of lymphedema in the limbs, both arms and legs. ImpediMed's L-Dex U400 BIS device is the only known device on the market that evaluates post lumpectomy, post lymphectomy cancer patients in this manner

Use of this device will allow Central Arkansas Veterans Healthcare System (CAVHS) staff to spot early non-clinical signs of lymphedema and help prevent the occurrence in post-surgical patients, thus reducing health care costs and providing for a better quality of life. CAVHS PMRS has three certified lymphedema specialists qualified to use this unit at this time.

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

The Contracting Officer will ensure posting requirements to Federal Business Opportunities (FBO) are followed IAW FAR Part 6.302-1. As ImpediMed Inc. is the only known manufacturer competition amongst more than one source has been deemed impracticable by the Contracting Officer based on the considerations set out above.

**7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:**

ImpediMed's L-Dex U400 device has been sold to not only the general public but also to agencies of the Federal Government. The contracting officer shall determine price reasonableness in the basis of market research in accordance with Federal Acquisition Regulation (FAR) 13.106-3 (a) (2)(ii) comparison of the proposed price with prices found reasonable on previous purchases; and FAR 13.106-3 (a) (vii) any other reasonable basis.

**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 concerning electrical impedance to assess early fluid retention to diagnose lymphedema in the limbs, both arms and legs and it was discovered there are no other known manufacturers currently in the market place. In addition, ImpediMed Inc. is a small business concern under the NAICS code selected for this procurement.

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

NA

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

NA

**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:**

Market research conducted in July 2013 indicated that the sole manufacturer of the device required by CAVHs PMRS is ImpediMed Inc. As this is anticipated to be a one-time purchase, no additional actions for future procurements are being conducted.

**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.

X Rachel E. Bouyer 8/9/2013  
Requestor/Certifying Official

**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.

Jennifer Johnson  
Jennifer Johnson  
Contracting Officer  
SAO Central

8/9/13  
Date

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

Kimberly C. Hurt  
Kimberly C. Hurt  
Chief of Regional Contracting  
SAO - Central Region

8/23/2013  
Date