

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

**1. Contracting Activity:** Department of Veterans Affairs, NCO 10, Chillicothe VA Medical Center Contracting has prepared this document to serve as the "Justification for Other Than Full and Open Competition" for PR# 538-13-4-087-0091.

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

This procurement is a firm-fixed-price action to secure a Neurostar and accessories for the Chillicothe VA Medical Facility. Neurostimulation is a quickly evolving field looking at novel ways of treating specific types of unipolar depression without the systemic effects seen with medication. Clinical research is also being done in Bipolar Depression, Anxiety/Panic Disorders, Post Traumatic Stress Disorder, and other areas which might expand the indications for NeuroStar TMS Therapy.

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

- Neurostar
- Neurostar Installation
- Neurostar On-Site Clinical Training
- SenStar Disposable Treatment Links Qty 100

**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):**

The NeuroStar device is the only commercially available FDA approved device for Transcranial Magnetic Stimulation. Neuronetics, Inc. is the exclusive proprietor and sole distributor of the NeuroStar TMS System (Proprietary letter submitted with eCMS package). The NeuroStar delivers transcranial magnetic stimulation for the treatment of Major Depressive Disorder. NeuroStar was cleared by the FDA in 2008. There are currently over 500 NeuroStar locations in the United States. This is a highly specialized system for the treatment of several mental disorders/ handicaps.

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

The customer and CS reviewed the NAC and GSA ECAT and found nothing comparable (sources sought conducted via GSA EBuy). Neuronetics, Inc confirmed it is the only provider of this FDA approved Transcranial Magnetic Stimulation device. Sole source requirement no other source is able to provide this product due to proprietary rights. Proprietary letter is provided in eCMS package.

**7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The quote by Neuronetics is consistent with their market pricing for the requested device(s).

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

Neuronetics, Inc is the only provider of this FDA approved Transcranial Magnetic Stimulation device. Sole source requirement no other source is able to provide this product due to proprietary rights. Proprietary letter is provided in eCMS package.

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

Sole manufacturer and distributor of the requested equipment.

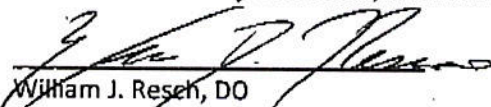
**10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**

Neuronetics, Inc.  
3222 Phoenixville Pike  
Malvern, PA 19355  
Sara Mueller, Sales Representative 513-470-4175

**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:**

Continued research and development has been and will be evaluated and observed for any new entrants into the market for the treatment of severe nonprescription responsive depression. The market will continually be surveyed for new developments and new entrants into the arena that will best serve the Veterans at the Chillicothe VAMC.

**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.

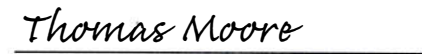
  
William J. Resch, DO  
Consult Liaison Psychiatrist  
Chillicothe VA Medical Center

7-31-13

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.

  
THOMAS P MOORE  
CONTRACTING OFFICER  
NCO 10

7/31/2013

Date

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

FOR   
TERRY SPITZMILLER  
NETWORK CONTRACT MANAGER  
NCO 10

7/31/2013

Date