

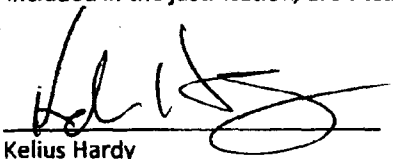
DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A)  
For  
Other Than Full and Open Competition (>SAT)

Acquisition Plan Action ID: 36C246-18-AP-7325

1. **Contracting Activity:** Department of Veterans Affairs, VISN 06, Hampton VA Medical Center, 100 Emancipation Drive, Hampton VA 23667, PR# 652-19-1-116-0002
2. **Nature and/or Description of the Action Being Processed:** This requirement is for a brand name only request to supply the Richmond VAMC with Medtronic Bone Tamp Trays. This requirement will be a base contract with 4 option years.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The Richmond VAMC will use these items to aid in the treatment of acute fractures of the thoracic and lumbar spine. Kyphon™ Balloon Kyphoplasty uses orthopaedic balloons to restore vertebral height and correct angular deformity due to vertebral compression fractures (VCFs). After reduction, the balloons are deflated and removed. The resulting cavity (void) allows for a controlled deposition of Kyphon bone cement forming an internal cast and stabilizing the fracture. The anticipated dollar value for this acquisition is; [REDACTED]
4. **Statutory Authority Permitting Other than Full and Open Competition:**  
  
*FAR13.5 Simplified Procedures for Certain Commercial Items: The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).*
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 Richmond VAMC has standardized their practices on the Medtronic platform. This is the only device on the market that uses a balloon to create a cavity in the broken vertebral body to help reduce the fracture to more normal shape and create a space for cement to fill and strengthen the broken vertebral body. This particular system is very well studied and has the greatest market share with excellent short and long-term results. No other vendor for spine fixation offers this treatment method.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** The items needed for this acquisition are proprietary to Medtronic. Market research efforts have determined that Medtronic has 3 authorized SDVOSB resellers/distributors. Pursuing this acquisition as a 100% SDVOSB set-aside will satisfy the VA Rule of Two and ensure maximum effort regarding competition for this acquisition.

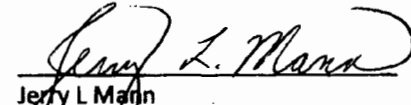
7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** The contracting officer will ensure that fair and reasonable pricing is obtained for this acquisition. The contracting officer believes that the 100% SDVOSB set-aside is the most advantageous avenue to take regarding receiving fair and reasonable pricing. Fair and reasonable pricing will be determined prior to award based on competition.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research efforts involved confirming that Medtronic was the proprietor/manufacture of the items in need and determining if they had any authorized distributors/resellers. Once it was determined that Medtronic had several SDVOSB resellers, the contracting officer realized that the VA Rule of Two would apply and a 100% SDVOSB set-aside could be pursued.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** N/A
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**
- Medtronic USA Inc.  
6743 S Point Drive N  
Jacksonville, FL 32216-6218  
DUNS: 078281737
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 Richmond VAMC has standardized on the Medtronic platform and thus, no actions have been taken to overcome or remove barriers to competition. The Medtronic Eone Tamp Kits offer a technology/flexibility not found in other vendor's spine fixation treatment methods. Switching to another spine fixation method would undermine current standardization efforts and would result in a training burden with increased costs that are not anticipated to be recouped through a competitive acquisition for a new platform.
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.

  
Kelius Hardy  
Inventory Manager  
Richmond VAMC

8/27/2018  
Date

**13. Approvals in accordance with the VHAPM Part 806.3 OFOC SOP:**

- 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.

  
Jerry L Mann  
Contracting Officer  
Supply Team 2

9/10/18  
Date:

- b. **One Level Above the Contracting Officer (Required over S/T but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

John Kopp 169202 Digitally signed by John Kopp 169202  
Date: 2018.09.10 07:51:20 -04'00'

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John Kopp  
Division Chief  
Supply Team

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Date: