

**DEPARTMENT OF VETERANS AFFAIRS**

**Justification and Approval (J&A)**

**For**

**Other Than Full and Open Competition (>\$150K)**

1. **Contracting Activity:** This Justification for Other Than Full and Open Competition is prepared by the Department of Veterans Affairs Network Contracting Office 6 (NCO 6) on behalf of the Veterans Affairs Medical Center in Richmond, VA in support of Purchase Request No. [REDACTED]

2. **Nature and/or Description of the Action Being Processed:** This is an individual justification and approval for a new award. This justification provides the rationale for contracting by other than full and open competition to acquire a PRO –Axis spinal bed with controlled advanced hinge technology.

This procurement is for a PRO –Axis spinal bed with controlled advanced hinge technology in accordance with FAR 13.5 Test Program for certain commercial items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2. A firm fixed purchase order will be awarded on a sole source basis to Mizuhosi Orthopedic System Inc with an estimated delivery 30 days after receipt of order (ARO).

3. **Description of Supplies/Services Required to Meet the Agency’s Needs:** PRO –Axis spinal bed with controlled advanced hinge technology. The estimated value of the proposed action is [REDACTED]

- proAXIS 1(EA.)
- Assy. Cervical Traction Vector, Short 1(EA.)
- Retractor Adaptor 2(EA.)
- Pillow, Positioning, STD 4(EA.)
- Positioning Pad Set Tempur-Med (6 pc) 1(EA.)
- Universal Side Rail Adapter 3(EA.)
- Cervical Management Base Unit 1(EA.)
- PKIT, PV, W/ACP. proAXISTM, (6/CS) 1(EA.)
- ISVP 1(EA.)

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):** Positioning on the surgical table is one of the most vital phases in any spinal surgical procedure. The ideal position for spinal surgery should facilitate exposure, lessen equally bleeding and the probability of harm to vital structures, and allows suitable ventilation of the sedated patient. The consequences of improper intraoperative positioning can be profound: it not only may cause substantial morbidity but also may be a major area of litigation, particularly when peripheral nerve injury occurs. The three commonly used bed frames for spinal surgery are the Wilson, Andrews, and Jackson. They all provide a fixed, stable method of maintaining patients in a flexed position. The unique capability of the PRO-Axis allows flexing during the surgery procedure rather than requiring the patient remain in a fixed position.

The PRO-Axis is the only spinal surgery bed, which enables the surgeon to flex the spine during surgery to maximize the natural curvature of the spine thus giving a natural posture. When surgery is done on other frames, it is not possible to achieve natural curvature. The inability to achieve the natural curvature results in an unnatural posture. The table's positioning and operating functions are controlled by an intelligent hand pendant, which is proprietary to Mizuhosi. Mizuhosi Orthopedics Systems Inc. is the manufacturer and sole distributor of the PRO-Axis surgery table. The benefit achieved from the PRO-Axis bed/table is an enhanced level of patient care. Accordingly, the PRO-Axis is the only brand capable of meeting the need without the VAMC Richmond experiencing substantial duplication of cost not expected to be recovered through competition.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A notice of intent to award on a sole source basis to Mizuhosi will be posted on [www.fbo.gov](http://www.fbo.gov) IAW FAR 13.501(a)(1)(iii). While it is not a request for quotation, any response that shows clear and convincing evidence that competition would be advantageous to the Government will be considered for future requirements.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** In accordance with FAR 13.106-3, Award and Documentation, comparison of the proposed prices found reasonable on previous purchases will be used to determine that the proposed prices are fair and reasonable based on market research.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** In accordance with FAR 10, Market Research, a sources sought notice has been published to the FBO website. JLS Medical Products Group submitted product information for the Allen Spine System and Beacon Point Associates provide information regarding the OPERON D Series. Both systems were previously evaluated deemed incapable of meeting the standards of the Richmond VAMC.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:**
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**

Chapter VI: Other Than Full and Open Competition (OFOC) SOP  
Attachment 3: Request for Sole Source Justification Format >\$150K

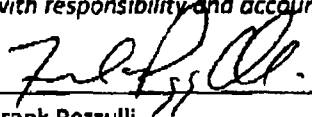
- Mizuhosi Orthopedics Systems (small business), 30031 Ahern Ave Union City CA 94587-1234
- JLS Medical Products Group (VOSB), 182 Summerside Drive New Braunfels, TX 78132
- Beacon Point Associates, LLC (SDVOSB), 21011 Johnson Street, Suite 109, Pembroke Pines, FL 33029

**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:** For future requirements and subsequent acquisitions of this type, in order to overcome any barriers to competition, market research will be used as a guide to determine whether or not the market for competition exists. The appropriate procurement strategy will then be determined and followed. The contracting agency will continue to monitor the market for the inception of other companies capable of meeting the requirement.

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Attachment 3: Request for Sole Source Justification Format >\$150K

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.

(This signature is the requestor's supervisor, fund control point official, chief of service, someone with responsibility and accountability)

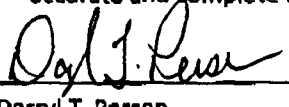
  
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Frank Pezulli  
Hunter Holmes McGuire VAMC

04 Feb 2015  
Date

13. **Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP.**

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

  
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Darryl T. Person  
Contracting Officer  
NCO 6

2/5/15  
Date

b. **Quality Assurance (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

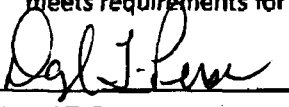
Kenneth M. Hood  
431913

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0.9.2342.19200300.100.1.1=kenneth.hood2@va.gov,  
cn=Kenneth M. Hood 431913  
Date: 2015.02.06 13:05:18 -0500

Jeffery A. Benton  
Quality Assurance Compliance Officer  
NCO 6

\_\_\_\_\_  
Date

c. **Director of Contracting /Designee (Required \$150K and above):** I certify the justification meets requirements for other than full and open competition.

  
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Darryl T. Person  
Commodities Branch Chief  
NCO 6

2/5/15  
Date