DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA260-18-AP-4676/648-18-3-9961-0096

1. **Contracting Activity:** Department of Veterans Affairs, Network Contracting Office (NCO) 20 on behalf of the VA Portland Healthcare System

2. **Nature and/or Description of the Action Being Processed:** This J&A is for a brand-name acquisition for the Portland VA Medical Center Operative Care Service. This will be a new, open market firm-fixed-price contract for the purchase of 15 new Stryker F1 Small Bone Power Tools.

   FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for commercial supplies in accordance with FAR 13.5 Simplified Procedures 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.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** This requirement is for the replacement of surgical small bone power tool systems, manufactured by Stryker. The total approximate value of $339,250.00 includes the following:

F1 Sag Saw	15 ea
F1 Micro Drill	15 ea
F1 U-Driver	15 ea
F1 Wire Collet	15 ea
F1 Small AO Chuck	15 ea
F1 5/32" Chuck	15 ea
Perforated Container	15 ea
Pencil Battery Pack	30 ea
Pistol Battery Pack	30 ea
Charger	2 ea

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 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):** This requirement is for direct

replacements of aged units currently on hand. The Stryker F1 series tools are compatible with the existing system. The replacement units will utilize the same accessories (saw blades, microdrills, etc) as the current units. This means that all accessories currently on hand can continue to be utilized. Replacement of all accessories would be a substantial duplication of cost to the government.

Moreover, the surgeons at the VA Portland Healthcare System are experienced and trained in the use of Stryker small bone power tools and have reported optimal results in its use. The criticality of this equipment as used in surgical procedures is such that variations in design, usibility and operation increases the risk of adverse patient outcomes and increases patient safety concerns. Standardizing operative equipment is a recognized best-practice for reducing the risk of errors, increasing uniformity of practice and patient safety. See Zhang, J. et al., Evaluating & Predicting Patient Safety for Medical Devices with Integral Information Technology, in Advances in Patient Safety: From Research to Implementation, Vol 2: Concepts and Methodology (Kerm Henriksen et al. eds., Agency for Healthcare Quality and Research 2005).

Lastly, this requirement is for specialized surgical equipment which has been approved for use by the facility Clinical Products Review Committee (CPRC). Per VHA Directive 1761 (1), the CPRC is responsible for reviewing and approving all new Reusable Medical Equipment (RME) prior to their use for direct patient care so that compatibility with current processes and equipment is ensured.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Market research was conducted to identify potential sources and the best method of acquisition. In addition to VIP, established contracts, GSA and FPDS, a sources-sought synopsis, 36C26018Q9610, was issued on July 19, 2018. Because this requirement is subject to the NMR, the sources-sought requested information related to manufacturers of small bone power tools. Responses came in from three SDVOSB distributors representing two large OEMs of bone tools, Stryker and ConMed. Product information was received for ConMed's system; however, the specifications did not meet the minimum requirements identified in the salient characteristics. Stryker, the second OEM responded by providing a letter of proprietary rights and a list of authorized resellers – two SDVOSBs and one SB.

7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** This is a commercial item; therefore, price analysis will be conducted prior to award to determine price reasonableness. Fair and reasonable pricing will be established through competition and a comparison to prices historically paid for similar items.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:**
   As described in Section 6 above, market research, in accordance with FAR Part 10, was conducted by synopsis of the proposed acquisition, advising industry of the pending acquisition and soliciting inquiries from interested parties. This includes a search on VIP, strategic source listings, GSA's eLibrary and FPDS for past acquisitions with similar requirements. Market research determined that this requirement is not available on FSS. In addition, market research determined that there there is not a NMR class waiver for NAICS 339112. Therefore, this acquisition will be solicited as a brand-name, unrestricted open market requirement.

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

These are direct replacements for existing units are aged and are beginning to fail. The NMR waiver process is lengthy and would unnecessarily delay the delivery of mission critical items. This course of actionensures the best possible pricing and reduces the risk of delays in access for patient care.

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

Stryker Healthcare Systems
Instruments Division
4100 E Milham Ave
Portage, MI 49002

Beacon Point Associates, LLC
1216 SE 4th Street, Suite 4
Cape Coral, FL 33991

TrillaMed, LLC
30100 Telegraph Rd.
Bingham Farms, MI 48025

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: Standardized medical equipment is a bona fide clinical need for patient safety. Future changes in available technologies or standards will require review and approval from the facility Clinical Products Review Committee (CPRC). However, market research will continue to be completed for all subsequent acquisitions to identify changes in the market and to promote competition from authorized sources.

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.

GORDON P HOSODA 583943 Digitally signed by GORDON P HOSODA 583943 Date: 2018.08.08 14:07:23 -07'00'

Gordon Hosoda
Chief, Healthcare Technology Management
VA Portland Healthcare System

08/08/2018
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.

Jacob P. Jackson 457690

Digitally signed by Jacob P. Jackson 457690
Date: 2018.08.23 08:02:18 -07'00'

Jacob P. Jackson
Contracting Officer, Supply Branch II
Network Contracting Office 20

Date

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

Jonathan D. Jewel 198381

Digitally signed by Jonathan D. Jewel 198381
Date: 2018.08.23 08:42:11 -07'00'

Jonathan Jewel
Branch Chief, Supply Branch II
Network Contracting Office 20

Date