DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: 36C260-18-AP-0981 / 648-18-3-9961-0206

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 is a new requirement to supplement existing electromedical units for the VA Portland Medical Center Advanced GI Procedural Suite. This procurement will be set aside for SDVOSBs under FAR 13, Simplified Acquisition Procedures.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The estimated value of the proposed action is $42,656.00. This is a brand name justification for the following:

PillCam® recorder DR3	5 ea
PillCam™ Sensory Array 2T, DR3 8-lead (SB)	1 ea
PillCam® sensor sleeves 10-pack	1 ea
PillCam® sensor belt 2T DR3 SB3	4 ea
PillCam® sensor belt 2 disp kit 5-pk	1 ea
PillCam® recorder DR3 cradle kit	5 ea
RAPID Software Kit, v8	1 ea
PillCam® SB 3-EX capsule 10-pack	1 ea

4. **Statutory Authority Permitting Other than Full and Open Competition:** 41 USC §3304(a)(1), as implemented by FAR 6.302-1.

   (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 per 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 Medtronic/Covidien PillCam® system is supplementing current PillCam® electromedical units. This requirement is for specialized procedural 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.

   The need for standardizing procedural equipment is critical as different models have slightly different operating procedures and user interfaces. A mixture of different models in the procedural suite increases the risk of user error, significantly increasing the risk to patient safety. Standardizing procedural 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: From Research to Implementation, Vol 2: Concepts and Methodology (Kerm Henriksen et al. eds., Agency for Healthcare Quality and Research 2005).

   Furthermore, standardization of equipment reduces the overall cost to the Government as it enables the Government to benefit from strategic, centralized procurement of consumables and components. The VA Portland Healthcare System currently uses the PillCam® system which is proprietary to Medtronic/Covidien. To purchase items from a different manufacturer would require the replacement of ancillary equipment and would represent an excessive duplication of costs to the Government.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Market research identified that there is a NMR class waiver for NAICS 334510, FSC/PSC 6525. Therefore, a search was conducted to determine if there are any authorized retailers of the required equipment. Review of a prior Brand Name Justification and approval revealed two OEM authorized distributors for Medtronic/Covidien. Telephone contact was made with each, and each confirmed verbally they are authorized distributors. One (Beacon Point Associates) confirmed in writing via email. A review of their capability statement and Authorized Vendor Letter indicates that they are capable of fulfilling this requirement. Therefore, offers will be solicited on FBO as a SDVOSB set-aside IAW 38 USC 8127.

7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated cost to the Government will be Fair and Reasonable 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 was conducted to determine if there are any authorized retailers of the required equipment. This includes a search on VIP, strategic source listings, GSA's eLibrary and FBO.gov for past acquisitions with similar requirements. Market research identified that this is available through SDVOSB OEM authorized sources. As described in Section 5 above, in accordance with FAR Part 10, market research was conducted by soliciting inquiries from interest parties. Two SDVOSB sources indicated interest and confirmed that they are OEM authorized distributor, one verbally and one in writing. A review of their capability statement and Authorized Vendor Letter indicates that they are capable of performing. Therefore, it is expected that there are two or more verified SDVOSB sources that are able to meet the requirement.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** The GI procedural rooms are not designated for use by a single physician; physicians schedule the use of one or more rooms as needed and can be working out of any of the suites. Therefore, the VA has a legitimate need to standardize the equipment it uses in the Advanced GI Care Service to achieve the highest possible reliability and effectiveness.

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

Covidien Sales LLC
3555 Koger Boulevard Suite 200
Duluth, GA 30096
(770) 662-0870
DUNS: 078672022
Other Than Small Business

Beacon Point Associates, LLC
1216 SW 4th Street, Suite 4
Cape Coral, FL 33991
(239) 673-6965
DUNS: 078717364
SDVOSB

Listing of Sources that Expressed, Verbally, an Interest in the Acquisition:

Veterans Healthcare Supply Solutions
13949 Alvarez Road, Suite 300
Jacksonville, FL 32218
(904) 638-5519
DUNS: 96489983
SDVOSB

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 ensure promotion of 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

Christian M. Navarro 980636 Digitally signed by Christian M. Navarro 980636 Date: 2018.08.30 12:07:23 -07'00'

CHRISTIAN NAVARRO
Inventory Management Specialist
VA Portland Healthcare System

8/30/18
Date

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

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.

Jackie L. Merriman 126679 Digitally signed by Jackie L. Merriman 126679 Date: 2018.09.04 11:32:06 -07'00'

JACKIE L. MERRIMAN
Contracting Officer
Chief, Medical Sharing 1, NCO 20

9/4/18
Date