

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A) For Other Than Full and Open Competition (>\$150K)

Acquisition Plan Action ID: VA261-17-AP-8219

- 1. Contracting Activity:** Department of Veterans Affairs, VISN 21, Network Contracting Office proposes a firm-fixed price contract on the basis of justification for other than full and open competition for the San Francisco VA Medical Center (SFVAMC). This purchase request is to acquire Preventative Maintenance, Repair, and Support Services for Medtronic Stealth Navigation Systems. The Period of Performance is one Base Year and three 1-year Options, starting from October 01, 2017 to September 30, 2021, totaling [REDACTED] for the four (4) years. The purchase request number is 662-18-1-067-0009 in the amount of [REDACTED]
- 2. Nature and/or Description of the Action Being Processed:** Using NAICS code 811310, this U.S. industry comprises establishments primarily engaged in repairing and maintaining electronic and precision equipment. Establishments in this industry repair and maintain equipment, such as medical diagnostic imaging equipment, measuring and surveying instruments, laboratory instruments, and radar and sonar equipment. These services can be used for purposes other than governmental and are commonly offered and sold to the public and to other non-governmental entities. Market research has determined the nature of this service to be a commercial services industry.

This coverage is required because proprietary parts and diagnostic information are only available to trained field technicians provided by the manufacturer, Medtronic, Inc. The Medtronic StealthStation S7, O-Arm, and Fusion ENT Navigation needs to be serviced and maintained; proprietary parts and diagnostic information are only available by trained field technicians provided by the manufacturer. These systems also need to be repaired if they are broken. The service contract includes all parts and labor, 24/7 phone support, and one Preventative Maintenance per year and per system.

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is Preventative Maintenance, Repair, and Support Services for Medtronic Stealth Navigation Systems 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:** The vendor is to provide Preventative Maintenance, Repair, and Support Services for Medtronic Stealth Navigation Systems for the San Francisco VA Medical Center. Medtronic, Inc. is the proprietary vendor which has complete customer and 24/7 technical support to assist with a variety of requests parts and labor, upgrades and service essential for completing preventative Maintenance, repair, and support Services for Medtronic StealthStation S7, O-Arm, and Fusion ENT Navigation. The period of performance and amount are as follows:

Period of Performance	Amount
Base Year: October 1, 2017 - September 30, 2018	
Option Year One: October 1, 2018 - September 30, 2019	
Option Year Two: October 1, 2019 - September 30, 2020	
Option Year Three: October 1, 2020 - September 30, 2021	
Grand Total:	

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;

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):

Medtronic Surgical Technologies is the exclusive equipment manufacturer of the Medtronic StealthStation S7, O-Arm, and Fusion ENT Navigation. These systems and instruments are medical devices subject to federal regulations. Medtronic does not authorize customers or third party repair entities to service these Medtronic products, including the loading or reloading of software. Any unauthorized service or modification to Medtronic systems or instruments will void existing warranties or service agreements. Additionally, Medtronic does not sell parts for service and repair to customers outside of any shared service programs. Medtronic does not authorize the service of its products nor sell parts to third party service/repair companies.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable: Medtronic, Inc. is the sole source for providing preventative maintenance, repair, and support services for the Stealth Navigation Systems. This requirement will be synopsized because it meets the threshold IAW FAR 5.101(a)(1).

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The Independent Government Estimate (IGE) is based on the historical data of the previous contract, VA261-17-P-0002. Based upon a comparison to the price of the same service awarded by previous contract, the anticipated cost to the government of [REDACTED] each year for a total base plus three years of \$ [REDACTED]. The previous two contracts, VA261-17-P-0002 and VA261-16-P-0773, rate per year for the same services was the exact same price at [REDACTED] per year. Both of the previous contracts were determined fair and reasonable IAW FAR 13.106-3(a)(2)(ii).
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** A general inquiry was performed to identify alternative service providers utilizing the SBA Dynamic and VetBiz sites however, no SDVOSB, VOSB, or small businesses could be identified. Due to these circumstances, it has been deemed only one source is available due to the specific patented and proprietary characteristics of the already installed/performing equipment that limits the availability to a sole source, Medtronic, Inc.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** There are specific patented and proprietary characteristics of the already installed/performing equipment that limits the availability to a sole source. Any replacement parts and service must be compatible in all aspects (form, fit and function) with existing systems presently installed/performing.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Medtronic, Inc., 710 Medtronic Pkwy, Minneapolis, MN, 55440-5603. DUNS No. 006261481
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:** Unless Medtronic, Inc. releases their patented and proprietary rights to the Stealth Navigation Systems, there are no other actions that can be taken to remove or overcome barriers to competition at this time. The requirement is sole source due to the proprietary nature.
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.

[REDACTED]

- 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.

[Redacted Signature] _____
[Redacted Title]

- b. **One Level Above the Contracting Officer (Required over \$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

[Redacted Signature] _____
[Redacted Title]