

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: 36C248-19-AP-5066

1. **Contracting Activity:** Department of Veterans Affairs, VISN 08, VACHS Medical Center, NCO-8. Justification for single source award under transaction number 672-20-1-2563-0003
2. **Nature and/or Description of the Action Being Processed:** Procurement action is for the preventive and corrective maintenance on Cogentix CST 5000 Cystoscopes. The type of contract will be firm-fixed price.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Provide all labor, equipment and materials for the corrective and preventive maintenance of the Cogentix CST 5000 cystoscopes units. Contractor shall perform corrective and preventive maintenance in accordance with manufacturer's recommendations and procedures. Estimated value with four option years is \$365,000. Period of performance will be from October 01, 2019 to September 30, 2024.
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 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):** Accordingly, Laborie Medical Technologies, Corp. is the only firm capable of providing the services described in Section III above without the Veteran's Health Administration experiencing unacceptable delays in fulfilling its requirements. Laborie Medical Technologies, Corp is the Original Equipment Manufacturer (OEM) and sole distributor that manufactures, markets, sells and services the Cogentix CST 5000 Cystoscopes and complies with FDA Regulations. OEM must be used to perform preventive and corrective maintenance in this unit. In order to maintain the manufacturer specifications in accordance with FDA Class I, II, and III devices intended for human use. Replacement parts on a medical device

intended for human use. Additional information can be found on the FDA site under Premarket Notification (510k) at:

<http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarket/submissions/premarketnotification510k/default.htm> Original Manufacturer representative complies with the Government Requirements.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** On August 08, 2019, a sources sought was emailed to all SDVOSB's and VOSB's. The request for information inquired about their capability and interest to provide the service procured in compliance with equipment manufacturer recommendation. Furthermore, a sources sought was published in FBO on September 13, 2019 and closed on September 16, 2019 with no responses.
7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** The Contracting Officer anticipates cost will be considered fair and reasonable based on cost comparisons to previous Government services as indicated in FPDS which have been determined to be fair and reasonable.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Based on a Vendor Information Pages (VIP) searched using NAICS code 811219 and PSC J065, the Government has identified twenty-eight (28) SDVOSB's and VOSB's. On August 08, 2019, a sources sought was emailed to all SDVOSB's and VOSB's. The request for information inquired about their capability and interest to provide the service procured in compliance with equipment manufacturer recommendation.

American Writers Inc. responded interested on the requirement. The vendor was requested to provide a manufacturer certified or authorized service representatives letter authorizing their company to provide parts and services on the Cogentix CST 5000 Cystoscopes and no response was received as of September 11, 2019.

On September 13, 2019 another sources sought was published in FBO with no responses.

Furthermore, Laborie Medical Technologies has confirmed via email that they are the OEM and sole distributor that manufactures, markets, sells and services the Cogentix CST 5000 Cystoscopes.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** None
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** American Writers Inc. responded interested on the requirement. The vendor was requested to provide a manufacturer certified or authorized service representatives letter authorizing their company to provide parts and services on the Cogentix CST 5000 Cystoscopes and no response was received as of September 11, 2019.
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:** A sources sought will be posted on Federal Business Opportunities (FBO).
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,

VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP
Attachment 2: Request for Sole Source Justification Format >SAT

which are included in the justification, are accurate and complete to the best of my knowledge and belief.

Carlos Rivera Vazquez
Carlos A. Rivera-Vazquez
Biomedical Equipment Support Specialist
VACHS

9/18/19

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.

Maribel Santa de la Paz
Contracting Officer
VACHS

09/18/2019

Date

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

Jose I. Hernandez
Branch Chief Services
VACHS

Date