

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: 36C249-19-AP-1010

1. **Contracting Activity:** Department of Veterans Affairs, Network Contracting Office (NCO) 9 and Veterans Integrated Services Networks (VISN) 09 VA Medical Centers (VAMC), Justification for Other than Full and Open Competition to provide TrackCore Tissue and Implant Tracking . The Network Contracting Office (NCO) 9 is responsible for the proposed contracting action. The identifying purchase request is 603-20-1-117-0001.
2. **Nature and/or Description of the Action Being Processed:** The proposed action will yield a firm-fixed price (FFP) contract to provide TrackCore Tissue and Implant Tracking System services for VISN 9 VA Medical Centers. This system will provide the ability to accurately track tissue and implant inventory from order to implantation during patient care. In order to be compliant with Joint Commission and FDA standards, an accurate record of patient implants must be kept and tracked in the event of a recall. A new firm-fixed price contract with a base year and four (4) 1-year options is desired.

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for a VISN 9 Medical Center tissue and implant tracking system; 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 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 TrackCore Tissue and Implant Tracking System delivers a cost-efficient, easy-to-use software product for managing the chain of custody for tissues and surgical implants, while adhering to compliance regulations and Federal Standards. TrackCore's intuitive functionality provides for quick and accurate data retrieval, enhancing patient safety while minimizing administrative costs. The system is designed to utilize TrackCore to manage biological and non-biological implants.

It is a web-based software solution to track implants (e.g. tendons, bones, ligaments, skin, screws, mesh, etc.) through the hospital from the time they arrive through final use, return or disposal. The bar code-based system is thoroughly compliant with FDA and Joint Commission regulations and allows users to:

- Log activity beginning at the loading dock or other point of entry into the facility to final disposition.
- Track the date and time each implant was used or moved.
- Record each individual who handles the implant.
- Monitor package integrity, temperature range and expiration date/obsolescence for each implant.
- Maintain data to properly identify the disposition of recalled implants for up to 50 years.
- Provide tiered access for different levels of access per user.
- VA Office of Information and Technology (OI&T) Authorized To Operate (ATO) System.
- Accessibility of legacy data.

The TrackCore Tissue Tracking System takes away the labor intensive and error prone tediousness of manual tracking and replaces it with an easy-to-use, more accurate system. If non-conformance is found, due to non-traceability, the facility may potentially lose accreditation, jeopardizing or facing fines due to non-compliance. TrackCore interfaces with popular Electronic Health Record (EHR) systems and tissue vendors and there is also a non-biologic module that tracks orthopedic, synthetic and device implants.

The period of performance for this action is for a twelve (12) month base period and a four twelve (12) month option periods. The period of performance for the base year and four 1-year options is from 10/1/2019 through 9/30/2024. The total estimated price of the proposed action is \$431,000.00.

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 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):** The TrackCore Implant and Tissue Tracking System from LPIT Solutions is the only implant tracking tool available today that provides the complete scope of work that is required by VHA. This system effectively and efficiently tracks and manages all biological and non-biological implant inventory. Implant management requirements include the ability to directionally track all implants/products from donor to facility to patient and back. Per Joint Commission standards, it allows system users to quickly and accurately pull implant information related to recalls, to report, in real-time, current stock levels, par levels, alerts for expiring products and cost, the TrackCore system is ATO by the VA OI&T, provides tiered access for users, and requires no migration of over five (5) years of past data.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

Intent to Sole Source 36C24919Q0213 notice was posted to FedBizOpps from 3/25/2019 to 4/9/2019 advising industry of the pending acquisition and soliciting inquiries from interested parties. One response was received from Champion Medical Technologies, Inc.

After review of multiple systems for implant tracking that is currently available to VHA, it is noted that TrackCore is the only system that has the specific abilities for tracking and scanning of implant inventories. Multiple companies and products were reviewed that provide similar type services. Those companies are as follows: UDI/GraftTracker by Champion Medical Technologies, Pyxis Tissue and Implant Module by Carefusion, Tracs4Life by Biomedical Synergies, Inc. Other tracking technologies reviewed do not offer the same technology that TrackCore can provide.

These surveys of the market place have confirmed the VA's market research assumptions regarding the capability of industry not being able to meet the VA's needs for a tissue and implant tracking system that will meet the complete scope of work. The VA will proceed with a sole source procurement of a tissue and implant tracking system contract with LPIT Solutions, Inc. (DUNS: 802274428).

7. Determination by the CO that the Anticipated Cost to the Government will be Fair and

Reasonable:

The anticipated price is determined to be fair and reasonable based on FAR 13.106-3(a)(2):

(ii) Comparison of the proposed price with prices found reasonable on previous purchases: RHJ VAMC Charleston, SC contract 36C24718C0182 and VISN 9 contract VA249-14-C-0076.

(vi) Comparison to the Independent Government Cost Estimate (IGCE). Estimates are provided for the TrackCore System and software licensing.

Based on the historical data obtained within the past four (4) years showcasing awarded prices for same or similar types of service as the subject requirement; and the IGCE that was submitted with the procurement request, the anticipated cost to the Government is found 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: The tissue and implant tracking system provided by LPIT Solutions, Inc. is the only Joint Commission and FDA compliant, provides tiered access, is currently VA OI&T ATO certified, and data migration would not pose an issue.

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. It is the intent of the Government to award a sole source firm-fixed price contract to LPIT Solutions, Inc. to provide TrackCore Implant Tracking System services for the VISN 9 Hospitals.

VetBiz – VIP was unable to provide vendors capable of providing tissue and implant tracking. Therefore, it is determined that two or more veteran-owned small-businesses are not capable and are not likely to submit a quote at a fair and reasonable price.

- 9. Any Other Facts Supporting the Use of Other than Full and Open Competition:** As described in Section 5 above, the TrackCore Implant and Tissue Tracking System from LPIT Solutions is the only implant tracking tool available today that provides the complete scope of work that is required by VHA. Per Joint Commission standards, it allows system users to quickly and accurately pull implant information related to recalls, to report, in real-time, current stock levels, par levels, alerts for expiring products and cost.

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

(1) LPIT Solutions, Inc.
25 Commerce Ave. SE Ste. 200
Grand Rapids, MI 49503
DUNS: 102552015

(2) Champion Medical Technologies, Inc.
765 Ela Rd. Ste. 200
Lake Zurich, IL 60047-6305
DUNS: 198016458

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: No further actions are planned to remove barriers of competition for the subject requirement. The TrackCore Implant and Tissue Tracking System from LPIT Solutions, Inc. is a widely utilized system by

VA Medical Centers across the country. It is the only implant tracking tool available today that provides the complete scope of work that is required by VHA.

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.

Winthrop E. Payne 6-7-2019
Winthrop E. Payne Date
Louisville VAMC – Administrative Officer,
Surgery Services VHA

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.

Craig S. Ziegemeier 6/12/2019
Craig S. Ziegemeier Date
Contracting Officer, NCO 9

- 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.

Jackie Merriman
Jackie Merriman Date
Branch Chief Services West, NCO 9