

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA252-18-AP-2125

1. Contracting Activity:

Department of Veterans Affairs
VISN 12
Jesse Brown VA Medical Center
537-18-1-969-0065

2. Nature and/or Description of the Action Being Processed:

The Jesse Brown VA Medical Center (VAMC) located in Chicago, IL has the requirement for one (1) EP Lab Recording System (WorkMate Claris Recording System 120 with EP-4 Cardiac Stimulator). This procurement will be pursued as a firm fixed price contract under the authority of 41 U.S.C. 1901 Simplified Acquisition Procedures as implemented in FAR 13.501. 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:

<u>Line Item</u>	<u>Item Number</u>	<u>Description</u>	<u>Qty</u>	<u>Unit</u>
0001	H700124	WorkMate Claris Recording System 120 with EP-4 Cardiac Stimulator	1	EA
0002	Training	System training on changes in function, layout, operator features, etc.	1	EA
0003	Installation	Installation of system	1	EA

Delivery for the requested equipment is expected as soon as possible, as this purchase request was submitted with an "Emergency" status. The period of performance is a one-time delivery for each line item.

4. Statutory Authority Permitting Other than Full and Open Competition:

FAR 13.5 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 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 Jesse Brown VAMC EP lab is in need of St. Jude WorkMate Claris Recording System 120 with EP-4 Cardiac Stimulator to safely perform ablation procedures in the Electrophysiology Lab. This equipment is manufactured by St. Jude Medical S.C., Inc. ("USD"). The facility owns a WorkMate Recording System that has been in use for approximately 12 years and is in an end of life state and unrepairable. This unrepairable status is according to St. Jude Service Repair. The facility averages four-to-five ablation procedures weekly and is "fee-basing" (sending the patient to a facility nearby with desired capabilities) those procedures which would cost approximately \$150,000.00 per week. Thus, a [REDACTED] period of fee-based ablation procedures would cost more than a St. Jude recording system.

The Jesse Brown VAMC has a rapidly expanding Electrophysiology (EP) program. The lack of this equipment severely impacts its ability to treat Veteran cardiac arrhythmias. Purchasing a new system to replace the current end of life system will provide the facility with a seamless transition to minimize interruptions in the lab throughput. Additionally, the Edward Hines, Jr. VA Hospital – a nearby VA facility – is currently unable to perform ablations due to physician staffing.

The St. Jude WorkMate Claris Recording System 120 with EP-4 Cardiac Stimulator is a high-performance electrophysiology recording system for collecting, displaying and storing data from multiple sources in the EP lab to determine the source of arrhythmias in the heart. The St. Jude system is compatible with the facility's Philips EP lab equipment and Biosense Webster, Inc. Carto 3 cardiac mapping equipment. Other systems such as the GE recording system do not integrate into the Philips lab equipment and replacing the entire EP lab is estimated to cost approximately \$1,500,000.00 in addition to the approximate cost of a similar system to the St. Jude WorkMate Claris.

The St. Jude equipment utilizes unique Clear Wave technology signal acquisition, which enables confident diagnosis. It has fast post-pacing recover, high sample rates, and low baseline noise. The electrograms displayed on the high-resolution WorkMate Claris system assist with fast and accurate diagnosis. Without this equipment, the facility cannot analyze ECG tracings to pinpoint arrhythmia excitation location. It also cannot stimulate or pace cardiac tissue when ablating. Most consequentially, it would not be able to "pace out" of a third-degree heart block resulting in no heart rate and codes. Lack of this equipment also exposes patients to increased risk of ablating inaccuracy due to interruption in analyzing ECGs which can cause asystole or other fatal arrhythmias. Therefore, this system is essential for every ablation procedure performed in the EP lab, with the goal of providing the highest level of Cardiology care for Veterans.

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

This is a requirement for Brand Name Only Equipment. Therefore, quotation will be sought from a single source, the original equipment manufacturer, to ensure distributor markups are not incurred, no gray market items are purchased, and a streamlined and immediate purchase may take place.

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

Price will be determined fair and reasonable IAW FAR 13.106-3(a)(2)(ii): Comparison of the proposed price with prices found reasonable on previous purchases.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:

The Contracting Officer (CO) conducted a search on VIP VetBiz to determine if there are any Veteran-Owned Small Businesses (VOSBs) or Service-Disabled Veteran-Owned Small Businesses (SDVOSBs) are able to fulfill the requirement. One (1) SDVOSB is indicated to distribute St. Jude products. Searches were also conducted on the GSA Advantage! and NAC MedSurg catalogs, as well as the MedSurg Prime Vendor-Next Generation formularies. All returned zero results. However, since this requirement is classified with an Emergency status, no Brand Name Only competition will be sought.

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:

St. Jude Medical S.C., Inc. ("USD").

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 follow-on solicitation actions are planned unless the CO is unable to determine Best Value for the Government, to include price reasonableness.

Although Market Research shows no Small Business competition exists at this time, Class Waivers for NAICS 339112 (Surgical and Medical Instrument Manufacturing) and FSC 6515 (Medical and Surgical Instruments, Equipment and Supplies) may be provided to remove the Non-Manufacturer Rule barrier for set-aside consideration.

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.

Jim Hedman
Contracting Officer
NCO-12 Great Lakes Acquisition Center (GLAC)

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.

Michael Rosenthal
Contracting Officer
NCO-12 Great Lakes Acquisition Center (GLAC)

Date

- 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.

Alea Barnes
Branch Chief – Equipment
NCO-12 Great Lakes Acquisition Center (GLAC)

Date