DETERMINATION OF LIMITATION OF SOURCES

1. CONTRACTING ACTIVITY:

Department of Veterans Affairs, Network Contracting Office (NCO 21)

2. DESCRIPTION OF ACTION:

This action limits competition for the acquisition of an Atrial Appendage Closure Device for the the VA Palo Alto Health Care System.

3. DESCRIPTION OF SUPPLIES/SERVICES:

Medical device for soft tissue closure, 10 systems at er system.

Purchase Request: 640-13-2-580-0232

The estimated value is .

4. AUTHORITY CITED:

FAR 13.106(b)(1), only one source is reasonably available because only one manufacturer will meet the Government's needs.

5. REASON FOR AUTHORITY CITED:

The authority cited in paragraph 4 must be used because there are currently no other manufactures of Atrial Appendage Closure Devices that have capabilities of SentreHeart's LARIAT Suture Delivery Device. The LARIAT system has the unique combination of the following capabilities: Formable delivery catheter tip, Snare system that delivers non-absorbable suture, Collapsible and retractable snare, Device access through 4.3mm incision, and has the ability to close soft tissue up to 40mm in width, 20mm height and 70 mm length.

6. EFFORTS MADE FOR SOLICITING FROM OTHER VENDORS:

This requirement will be synopsized in the GPE as required by FAR 5.201.

7. FAIR AND REASONABLE COST DETERMINATION:

The Contracting Officer has determined that the anticipated price will be determined to be fair and reasonable. A Price Negotiation Memorandum (PNM) will detail how the Government has determined that the anticipated costs will be fair and reasonable.

As this item has been determined to be commercial, cost or pricing data will not be required. Pricing techniques such as are described in FAR 15.404-1(b)(2), will be used to establish price fairness and reasonableness.

8. MARKET RESEARCH:

Market Research was conducted by searching and reviewing FBO, FPDS, and eCMS. The GSA website was also reviewed for existing vendors that could satisfy the requirements. It was determined that the product was not available on GSA and that the product is only available from SentreHEART Inc. and no other suppliers can satisfy agency requirements.

9. SUPPORTING FACTS:

Review of the FDA website revealed that there are no "Equivalent" device manufacturers for SentreHEART's Lariat Suture Delivery Device.

SentreHEART's Lariat Suture Delivery Device utilizes patented technology, and as such, the company is the only manufacturer and vendor that can successfully satisfy the requirements for this purchase.

Any supporting data that is the responsibility of technical or requirements personnel (*e.g.*, verifying the Government's minimum needs or requirements or other rationale for limited sources) and which form a basis for the justification have been certified as complete and accurate by the technical or requirements personnel. The evidence for this is the "Technical Data to Support a Restricted Competition" in the contract file.

10. LISTING OF SOURCES:

SentreHEART, Inc
300 Saginaw Dr
Redwood City, CA 94063
(855) 258-7330

11. STATEMENT OF ACTIONS:

A notification will be issued that advises that the Government intends to procure via sole source. However, if any contractor believes they have an equivalent product, they are encouraged to contact the Contract Specialist for more information.

12. CONTRACTING OFFICER CERTIFICATION:

I hereby certify that this justification is accurate and complete to the best of my knowledge and belief.

Denard M. Fobbs Jr
Contract Specialist

4-22-13
Date

Recommend: Approval / Disapproval

Claire Ursino
Contracting Officer

4-22-13
Date