

DEPARTMENT OF VETERANS AFFAIRS
Justification and Approval
For
Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veteran Affairs, NCO 10 Contracting and VISN 10, Cleveland VAMC, Medical Service Justification for Other Than Full and Open Competition. Transaction: 541-14-3-250-0374.
2. **Nature and/or Description of the Action Being Processed:** NCO 10 proposes to issue a one-time, firm-fixed priced, purchase order, using other than full and open competition procedures.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The Cleveland VAMC Radiology Service has a requirement for a Mammotome Revolve ST System. This is an imaging guided breast biopsy system that directly connects to our existing mammography unit. The items listed below make up the required system. The estimated price is \$27,720.00 with a delivery date of 30 days ARO.

Product Code	Description	Qty.
REVOLVE1	Mammotome® revolve™ ST System (System Control Module, Cart, Keypad, Footswitch, ST Holster)	1
MC12-CM	Control Module - 1 year Mammotome Service Agreement	1
MST0812	8G, 12cm Length Mammotome® revolve™ ST Probe	2
MST1012	10G, 12cm Length Mammotome® revolve™ ST Probe	2
MMK0801	8G MammoMARK™ Biopsy Site Identifier BOWTIE Shape (use with 8G Mammotome® revolve™ Probe)	1
MMK1001	10G MammoMARK™ Biopsy Site Identifier BOWTIE Shape (use with 10G Mammotome® revolve™ Probe)	1
MCANISTER1	800cc Replacement Vacuum Canister (use with Mammotome® revolve System)	1
MG08B	8G Mammotome® revolve Disposable Probe Guide, button shape (for GE Upright Systems)	1
MG10B	10G Mammotome® revolve Disposable Probe Guide, button shape (for GE Upright Systems)	1

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

- (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;

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** A comparison of the Mammotome system and Hologic's system has indicated that Mammotome system is the preferred system for the following reasons:

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-The Mammotome biopsy system is a closed system, which provides better handling of pathology specimens whereas with the Hologic system, after the cores are captured, a container must then be opened and the specimens removed and then placed into another holding container allowing a greater chance for mishandling and contamination of specimens.

-While not the only vendor that can be made compatible with our current GE Senographe Mammography System, Mammotome and its devices have been made to be more retrofitted to the unit due to the fact that their company submitted themselves to GE during the planning phase of the add-on Stereotactic Device for the GE mammography unit.

-Thorough research of both vendors was completed as well as presentations made by both vendors here at the Louis Stokes VAMC, after which radiologist and technologist traveled to an outside facility to see both devices in real-time operation with real patients. Mammotome, hands down showed itself to be more patient friendly, providing closed containment of blood and fluids as well as better patient comfort. From set-up, operation and completion of a stereotactic procedure Mammotome was more time efficient. As a result, the Contracting has determined that it is in the best interest of the Government to procure the required equipment on a sole source basis.

Accordingly, Mammotome A Division of Devicor Medical Products, Inc. is the only firm capable of providing the supplies and services described in Section III above without the Veteran's Health Administration experiencing substantial duplication of cost that could not be expected to be recovered through competition and unacceptable delays in fulfilling its requirements.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A search was conducted on NAC/GSA and VA Advantage and no vendors were found that could deliver the needed device. Intent to Sole Source was posted on 8/8/2014 through 8/13/2014. One company, Hologic, Inc. responded stating that Hologic, Inc.'s device is compatible with the current system. The system was reviewed as indicated in question 5.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The price being offered to the Government is the same as would be offered to any institution public or private and the company has indicated that they are providing their best pricing. As a result, the Contracting Officer anticipates the cost to the Government will 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:** A search was conducted on NAC/GSA and VA Advantage and no vendor was found that could deliver the supplies. A search on the internet was conducted to see if there were any similar products and An Intent to Sole Source was posted on 8/8/2014 through 8/13/2014. One company, Hologic, Inc. responded stating that Hologic, Inc.'s device is compatible with the current system. Details of the evaluation are indicated in question 5.
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:**
Mammotome - A Division of Devicor Medical Products, Inc.
Hologic

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:** On-going research of the industry market place will be conducted to determine if there are new entrants into this product arena.

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.



William Precht
COR
VISN 10/Cleveland VAMC

9/3/14
Date

13. **Approvals in accordance with FAR 6.304** This contract action does not exceed \$650,000.00, the certification below required by FAR 6.303-2(b)(12) services as approval.

a. **Contracting Officer's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Thomas Moore

Thomas P. Moore
Contracting Officer
NCO 10

Digitally signed by Thomas Moore
DN: cn=Thomas Moore, o, ou=NCO 10,
email=thomas.moore9@va.gov, c=US
Date: 2014.09.03 16:42:58 -04'00'

Date

b. **NCM/PCM (Required \$3K and above):** I certify the justification meets requirements for other than full and open competition.

Terry Spitzmiller
Director of Contracting
Networking Contracting Office (NCO) 10

Date