

DEPARTMENT OF VETERANS AFFAIRS

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

1. **Contracting Activity:** Department of Veterans Affairs, VISN 16, Michael E DeBakey Medical Center, 2002 Holcombe Blvd, Houston, TX 77030 Vista Equipment Transaction number# 580-15-1-167-0042.
2. **Nature and/or Description of the Action Being Processed:** Justification and approval for Other Than Full and Open Competition, for Mammotome System for the new Breast Care Program in Radiology section Michael E DeBakey VA Medical Center, 2002 Holcombe Blvd, Houston, Texas 77030. Purchase Requests # 580-15-1-167-0042. Procurement action resulting in the sole source award of a new firm-fixed price contract to Devicore Medical Products for the Mammotome Breast Biopsy System, Estimated Value: \$
3. **Description of Supplies/Services Required to Meet the Agency's Needs:**  
The Mammotome system is a vacuum assisted breast biopsy system that uses image guidance such as x-ray, ultrasound and/or MRI to perform breast biopsies.
4. **Statutory Authority Permitting Other than Full and Open Competition:**  
  - (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;
  - The Mammotome system is the only system with a dual vacuum system, touch free breast biopsy collection system which automatically sorts tissue samples for radiographing, variable aperture setting, fluid management, and 200mg core samples.
  - Faxitron/Corevision Radiography system is in room Radiography device that allows us to confirm a successful biopsy without leaving the procedure room which helps to eliminate delays waiting for verification of core samples.
  - Mammotest Table- which brings optimized access through: angled targeting via polar coordinates, all-angles 360 degree access, target on Scout option, lateral arm option, arm-through-hole technique.
5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**

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- The Mammotome system is the only system with a dual vacuum system, touch free breast biopsy collection system which automatically sorts tissue samples for radiographing, variable aperture setting, fluid management, and 200mg core samples.
- Faxitron/Corevision which is in room Radiography device that allows us to confirm a successful biopsy without leaving the procedure room.
- Mammotest Table- which brings optimized access through: angled targeting via polar coordinates, all-angles 360 degree access, target on Scout option, lateral arm option, arm-through-hole technique.

The patient and provider spend less time in the biopsy procedure as a result. The procedure is less traumatic and therefore recovery is swifter. The wait time for diagnosis is also shortened. This system represents the standard of care for our Veteran population.

**6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** *This action was synopsised and published on the government Point of Entry, FedBizOpps.*

**7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable**

Overall system cost was a consideration when evaluating the various systems. In addition, price reasonableness will be determined by comparing price to historical data and/or independent government estimate. The item is available commercially, therefore a commercial price analysis can be conducted using past sales by the manufacturer to commercial, nonprofit, and government organizations.

**8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** We have conducted an extensive market research through online search, contacting several vendors, and talking to other VA facilities. Only Mammotome meets our requirements since they are the only one with dual vacuum breast biopsy system with advanced tissue management technology. In addition, the Mammotome system is touch free biopsy collection system which automatically sorts tissue samples.

**9. Any Other Facts Supporting the Use of Other than Full and Open Competition:** A thorough examination of the most suitable systems available was conducted by an evaluation team. After extensive review and discussion, the team consensus is the Mammotome System. The system fulfills capability and compatibility requirements and offers the best value to the Government.

**10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** A Sources Sought was published on FedBizOpps, and no sources expressed an interest in this acquisition. This J&A will be posted on FedBizOpps.

**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:** The

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DeviCore MammoTome represents the latest technology. We will continue to survey the market for the best ways of delivering quality care to our Veterans, keeping in mind that competition is the key to driving technology and favorable pricing.

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.

<b>Temenit Asgedom //TRA//</b>	<b>03/09/15</b>
Temenit Asgedom	Date
Medical Administrative Specialist, Diagnostic & Therapeutic Care	
Houston VAMC	

13. Approvals in accordance with the [VHAPM, Volume 6, Chapter VI: OFOC SOP](#).

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

Paul G Filhiol 664375  
PAUL FILHIOL  
Contracting Officer  
NCO 16 Div III Supply Team C 667 SHR

- b. Director of Contracting /Designee (Required \$150K and above): I certify the justification meets requirements for other than full and open competition.

Calvin Q. Ma 630986 Signature of Calvin Q. Ma (NCO)  
Do not sign this form on internet or e-mail.  
NCOIC 10000000, 100.11 (Contracting) of Calvin  
Q. Ma (NCO)  
Date: 2014.02.16 16:29:30

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AARON VILLALPANDO Date  
NCO 16 Director of Contracting (or Designee)