

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

1. Contracting Activity: Department of Veterans Affairs, Network Contracting Office 16, Michael E. DeBakey VA Medical Center (MEDVAMC), Houston, Texas

580-14-2-028-0113

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

This transaction is for the emergency purchase of IBV valves used during emergency Bronchoscopy surgery.

This is a firm fixed price contract.

3. Description of Supplies/Services Required to Meet the Agency's Needs:

The IBV Valve System is a minimally invasive treatment option for providers managing post-operative air leaks. The small umbrella-shaped valves are deployed into the airways of the lungs via a catheter passed through a bronchoscope.

\$82,500.00/the delivery date is January 30, 2014.

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):

The IBV Valves prevent air from flowing distally to the injured tissue while still allowing mucus to exit through normal ciliary transport. This reduction in the flow of air to injured lung tissue may promote healing and accelerate resolution of an air leak. The valves are later removed via a similar bronchoscopic procedure.

The IBV Valve System is a device to control prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged air leaks following lobectomy, segmentectomy, or lung volume reduction surgery. The valves are later removed via a similar bronchoscopic procedure. This is the only FDA approved bronchial valve for the control of post surgical air leaks.

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

Due to the emergent nature of this acquisition, no other vendors were solicited. Spiration Inc. is the only company that can provide the IBV Valve System and airway sizing kits.

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

A search of the FPDS shows no comparison in pricing data for these valves and kits. The hospital is in receipt of the pricing information for the vendor and informed contracting the pricing is the same for government and nongovernment entities. Due to the proprietary nature of this acquisition, no other vendor pricing was available for comparison. Reasonableness

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

A search of GSA and Google shows no other vendor information with these items.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition:

Due to the proprietary nature of this acquisition, no other vendor sought. But, there will be a continued effort to seek other vendors for valves and kits for compatibility with the existing equipment.

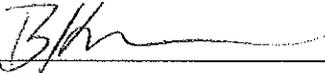
10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

Andrew Heppes, Spiration, Inc., 6675 185th Avenue N.E., Redmond, WA 98052, C: 241-668-6443, aheppes@spiration.com.

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:

Contracting will continue to search for comparable items from other vendors. A search of the internet does not show any other vendors with these items.

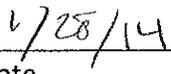
12. Requirements Certification: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.



Beena Kurian

Supervisory Health System Specialist

Michael E. DeBakey VA Medical Center, Houston, TX



Date

13. Approvals in accordance with FAR 6.304

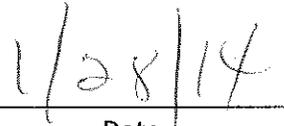
a. Contracting Officer's Certification: (required) I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



Vernester Ingram

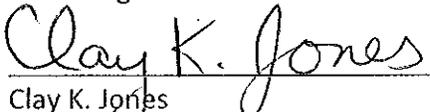
CONTRACTING OFFICER

G.V.(Sonny) Montgomery VAMC



Date

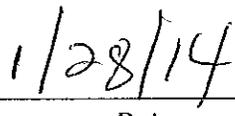
b. P&C: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



Clay K. Jones

CHIEF, PURCHASING AND CONTRACTING

NETWORK CONTRACTING OFFICE 16



Date