

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA263-16-AP-1341

1. **Contracting Activity:** Department of Veterans Affairs, NCO 23, Saint Cloud, MN 56303. Transcatheter Heart Valves. 2237 Number: 618-16-1-029-1072.
2. **Nature and/or Description of the Action Being Processed:** A firm-fixed priced contract to provide Edwards Lifesciences-Sapien Transcatheter Heart Valves and related Delivery System.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Edwards Lifesciences-Sapien Transcatheter Heart Valves and related Delivery System kits. To include the following:

- 23 mm Edwards SAPIEN XT Transcatheter Heart Valve (THV) with NovaFlex+ System
- 26 mm Edwards SAPIEN XT Transcatheter Heart Valve (THV) with NovaFlex+ System
- 29 mm Edwards SAPIEN XT Transcatheter Heart Valve (THV) with NovaFlex+ System
- 23 mm Edwards SAPIEN XT Transcatheter Heart Valve (THV) with Ascendra+ System
- 26 mm Edwards SAPIEN XT Transcatheter Heart Valve (THV) with Ascendra+ System
- 29 mm Edwards SAPIEN XT Transcatheter Heart Valve (THV) with Ascendra+ System

The estimated cost for this procurement is \$292,500.00

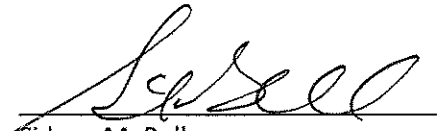
4. **Statutory Authority Permitting Other than Full and Open Competition:**

- (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;

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** Edward Lifesciences and Medtronic are currently the only two manufacturers that have FDA approval to provide transcatheter heart valves used in TAVR. Each veteran is evaluated prior to their surgical procedure to determine which type of valve and delivery system will provide the best surgical outcome. The Edwards Lifescience valves are less specialized valves that will better meet the needs of some veterans that are currently being evaluated for TAVR at the Minneapolis VA Health Care System. These sets of valves have the most applications that are not of a specialized nature. Medtronic does offer transcatheter heart valves, but these are more specialized in nature, and do not meet the needs of the all of the veterans that the TAVR program serves.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** The proposed action will be synopsized IAW FAR Part 5, with this Justification attached.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The price is fair and reasonable IAW FAR 13.106-3 (a) (2) (iv), based upon a comparison with similar items.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research was conducted both on GSA and open market sources. There are currently only two manufacturers that have FDA approval for transcatheter heart valves used in TAVR, Edwards Lifesciences and Medtronic.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** The government intends on making an award to both Edwards Lifesciences and Medtronic to ensure that multiple sized valves and multiple types of delivery systems are available to ensure that the veteran is receiving the valve through the delivery system that will provide best outcome for the veteran.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** None.
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:** If additional transcatheter heart valves are needed in the future, the government will conduct a survey of the marketplace to see if additional source are available, and if additional sources are found this requirement will be competed at this time.
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.


Sidney M. Bell
Logistics Officer
Minneapolis VA Health Care System

11/10/2015
Date

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.

ANDREA L
HARTER 197690

Digitally signed by ANDREA L HARTE
197690
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va.gov, cn=ANDREA L HARTE 197690
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11/10/2015

Andrea Harter
Contracting Officer, NCO 23

Date

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

Jennifer Myers-King
Branch Chief
NCO 23

Date