

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA263-16-AP-5465

1. **Contracting Activity:** Department of Veterans Affairs, NCO 23, Saint Cloud, MN 56303.
2237 Number: 618-16-2-029-4426.
2. **Nature and/or Description of the Action Being Processed:** A firm-fixed price contract to provide Boston Scientific WATCHMAN Left Atrial Appendage (LAA) Closure Devices and related access systems.

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for Left Atrial Appendage Closure Devices in accordance with FAR 13.5 Test Program for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Initial quantities of Boston Scientific WATCHMAN Left Atrial Appendage (LAA) Closure Devices and related access systems. To include the following:
 - 21mm WATCHMAN LAA Closure Device
 - 24mm WATCHMAN LAA Closure Device
 - 27mm WATCHMAN LAA Closure Device
 - 30mm WATCHMAN LAA Closure Device
 - 33mm WATCHMAN LAA Closure Device
 - WATCHMAN Access System, Single Curve
 - WATCHMAN Access System, Double Curve
 - WATCHMAN Access System, Anterior Curve

The estimated cost for this procurement is \$ 250,000.00

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;

FAR13.5 Simplified Procedures for Certain Commercial Items: *The authority for applying the Commercial Test Program of FAR 13.5 is (Section 4202 of the Clinger-Cohen Act of 1996) and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).*

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 WATCHMAN is the only device that currently has FDA approval for stroke risk reduction for closure of the Left Atrial Appendage. This procedure is minimal invasive, as it does not require open heart surgery to implant this device. This device is used to seal off the Left Atrial Appendage. Each veteran is evaluated prior to this procedure, and the physician has determined, that this procedure/device is the best course of treatment for this veteran.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A notice of intent will be posted on FBO.gov prior to award, with this justification attached.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The Contracting Officer will determine the price to be fair and reasonable prior to award IAW FAR 13.106-3 (a) (2).
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 on both GSA and open market sources. The WATCHMAN is the only device that currently has FDA approval for stroke risk reduction for closure of the Left Atrial Appendage.
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:** 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 in the future similar devices are needed, the government will conduct a survey of the marketplace to see if additional sources are available, and if additional sources are found this requirement will be competed at this time.