DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA263-18-AP-1895

1. <u>Contracting Activity</u>: Department of Veterans Affairs, Network 23 Contracting Office (NCO23), 4801 Veterans Drive, Saint Cloud, MN 56303

   2237 Number: 618-18-1-029-1537

2. <u>Nature and/or Description of the Action Being Processed</u>: A firm-fixed price, sole source purchase order for Sentinel Cerebral Protection System from Claret Medical, Inc.

   FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for Sentinel Cerebral Protection System in accordance with FAR 13.5 Simplified Procedures 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. <u>Description of Supplies/Services Required to Meet the Agency's Needs</u>: The Sentinel Cerebral Protection System is used when aTrans Arterial Valve Replacement (TAVR) valve is placed in the existing aortic valve. The Sentinel Cerebral Protection System captures and removes embolic material while performing TAVR, and reduces the risk of stroke during these procdures. This procurement is for 84 each of the Sentinel Cerebral Protection System

4. <u>Statutory Authority Permitting Other than Full and Open Competition</u>:
   (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 Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).

5. <u>Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority)</u>: Claret Medical, Inc. is the manufacturer and sole distributor of the Sentinel Cerebral Protection System. This is the only system that is FDA cleared for use during TAVR procedures.

6. <u>Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable</u>: This justification will be posed on FBO.gov in accordance with FAR 6.305.

7. <u>Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable</u>: The anticipated price is considered fair and reasonable, as the price represents a discount off of the commercial price, and is less than the price that has been determined fair and reasonable on previous purchases.

8. <u>Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted</u>: Market Research was conducted on the Vetbiz Registry, using NAICS code 339113 and the keywords "Claret" and "Sentinel", and no sources were identified. Claret Medical, Inc. is the manufacturer of the Sentinel Cerebral Protection System, they have no authorized distributors of this system.

9. <u>Any Other Facts Supporting the Use of Other than Full and Open Competition</u>: None.

10. <u>Listing of Sources that Expressed, in Writing, an Interest in the Acquisition</u>: None.

11. <u>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</u>: None.