

**DEPARTMENT OF VETERANS AFFAIRS**

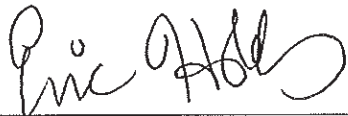
**Justification and Approval**

**For**

**Other Than Full and Open Competition**

1. **Contracting Activity:** Department of Veterans Affairs, VISN 11, *Ann Arbor, MI* Medical Center 506-14-3-041-1308, EV3 distributor and the manufacturer of the product requested.
2. **Nature and/or Description of the Action Being Processed:** The product requested will be used for upcoming surgeries in the Cardiology/EP (electrophysiology) lab for a special procedure. EV3, Inc., 3033 Campus Dr., Plymouth, MN 55441.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The Turbo Hawk™ Peripheral Plaque Excision System (Turbo Hawk Catheter and Cutter Driver) is designed for the treatment of de novo and retinoic atherosclerotic calcified and non-calcified lesions located in native peripheral arteries. When used in complex, hard, calcified lesions, the Turbo Hawk Catheter should be paired with the Spider FX™ Embolic Protection Device to mitigate any risk of distal embolization that may be generated by the breakdown of heavily calcified plaque. The Turbo Hawk Catheter consists of a flexible shaft designed to track over a 0.014" guide wire. At the distal end of the Turbo Hawk Catheter is a small cutting assembly comprised of a rotating inner blade contained within a tubular housing. The proximal end of the Turbo Hawk Catheter contains a connector and cutter positioning lever (thumb switch) designed to fit into the Cutter Driver. The Cutter Driver is a handheld, disposable, battery-driven unit (Catalog No. FG-02550), which powers the device. For information about the SpiderFX Embolic Protection Device, reference the Instructions for Use provided with the device. The hand held multi-electrode provides full-coverage, high-density map sample multiple points of cardiac mapping data simultaneously to reduce procedure & fluoroscopy time. Total: \$3,395.00, Date required: April 28, 2014.
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):**  
**Only One Responsible Source (FAR 6.302-1)**  
This product is unique and is used in special procedures and with other products that are already on hand. The physicians are familiar and trained using this product. EV3 is the only manufacture of the product requested no other manufacturer/distributor has these products. The High Efficiency (HE) Cutter is designed to give physicians the flexibility to treat all plaque morphologies, including heavy calcium. The HE Cutter employs off-the-wire flush cleaning using the Distal Flush Tool to remove calcified material.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** No efforts were made. EV3, Inc. is the only vendor that can provide these items.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** Price is determined fair and reasonable in comparison to the last purchase order for the same item, 506-A30550 \$3,444.00 (\$49.00 added for shipping).
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Internet was searched. No other vendors were identified that would be able to provide this item.
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:** EV3, Inc.
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:** No actions are currently available.
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.



Eric D. Hobbs  
Chief, Inventory Management, GIP  
VA Ann Arbor, MI

April 22, 2014  
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.

\_\_\_\_\_  
Name  
Title  
Network 11 Contract Office

\_\_\_\_\_  
Date

- b. **NCM/PCM (Required \$3K and above):** I certify the justification meets requirements for other than full and open competition.

\_\_\_\_\_  
Name  
NCM/Supervisory Contract Specialist (as appropriate)  
Network 11 Contract Office

\_\_\_\_\_  
Date