

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

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1. **Contracting Activity:** Department of Veterans Affairs, Healthcare System of Ohio, SAO Central Network Contracting Office (NCO) 10, VISN 10, Cincinnati, Ohio.

2. **Nature and/or Description of the Action Being Processed:** This is a one time purchase for the HALO<sup>FLEX</sup> System being procured on a sole source basis as a fixed price procurement for use in the ablation of bleeding and non bleeding sites in the gastrointestinal tract, including Barrett's esophagus.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The Cincinnati VAMC needs to upgrade the current generators: HALO Generator models 1100C-115B and 90-9000. This new specialized equipment to treat and prevent esophageal cancer. This request is for radiofrequency ablation devices that attach to inflatable balloons of various sizes to be utilized in the GI Lab/Ambulatory Surgery area. A special electrosurgical generator is required to apply the radiofrequency energy to the patient. The HALO<sup>FLEX</sup> Energy Generator offers "2 procedures in 1", providing the flexibility to choose either the balloon based circumferential HALO<sup>360+</sup> Ablation Catheter for larger treatment areas or the HALO<sup>90</sup> Ablation Catheters for smaller focal areas. The Barrett's Esophagus with dysplasia is a condition that places patients at very high risk of developing esophageal cancer, a very deadly and poorly treatable disease. The successful prevention of esophageal cancer by using the subject equipment will prevent much suffering and cost. The equipment includes: HALO flex energy generator, footswitch, output cable, and HALO cart. The estimated cost of this procurement is \$34,249.00

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)**

The requirement for the The HALO<sup>FLEX</sup> Energy Generator is required in order to upgrade to this new generation. The Halo Flex system offers a unique "2 procedures in 1" The Halo Flex system offers "2 procedures in 1", until recently patients with Barrett's esophagus with high or low grade dysplasia had two treatment options: continued endoscopic surveillance ("watchful

waiting”) or esophagectomy. Over the past several years there has been increasing interest in endoscopic ablation or removal of dysplastic Barrett’s esophagus. These procedures have focused on removing all or most of the Barrett’s esophagus (and therefore reducing the risk of cancer) in a safe and relatively non-invasive way. This system uses a flexible catheter with small electrodes on the end which can be guided endoscopically into the esophagus and used to ablate or burn the Barrett’s esophagus. Energy delivery is precisely controlled by a radiofrequency generator, so only the epithelial lining of the esophagus is ablated. The Proprietary bipolar electrode array delivers precise circumferential radiofrequency energy to the targeted tissue area and proprietary radio frequency bipolar electrode array delivers energy to targeted smaller areas of tissue. This second generation of HALO will allow use in other areas of the GI tract such as colon to treat radiation induced colitis and in the stomach we will be able to treat angiodysplasia. This capability does not exist with our current equipment.

**6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable.** This procurement was synopsised through a request for information (RFI) to GSA Advantage, VETBIZ and a CCR dynamic small business search.

**7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated cost is anticipated to be fair and reasonable to the government based on the using service’s IGCE and past procurements.

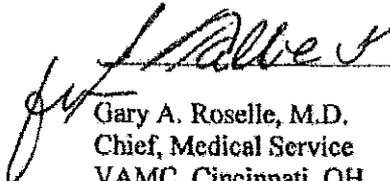
**Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research was conducted in accordance with FAR Part 10 utilizing GSA Advantage, VetBiz and CCR. An intent to sole source will be published on Federal Business Opportunities.

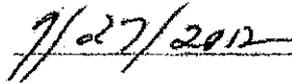
**8. Any Other Facts Supporting the Use of Other than Full and Open Competition:** The System equipment, Advanced Ablation Technology for Barrett's Esophagus, is provided on a commercial basis, but the only source of this specific brand of equipment is the BARRX Halo Generator System. No other sources can provide the HALO Flex Generator System equipment.

**9. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** None

**10. 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:** On-going research of the industry market place will be conducted to determine if there are new entrants into this product arena.

**11. 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.

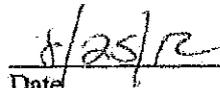
  
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Gary A. Roselle, M.D.  
Chief, Medical Service  
VAMC, Cincinnati, OH

  
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Date

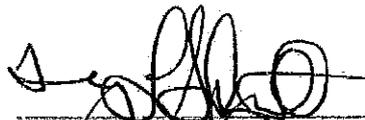
**12. Approvals in accordance with FAR 6.304**

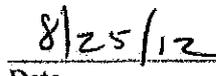
a. **Contracting Officer's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

  
\_\_\_\_\_  
Name  
Title: Contracting Officer  
Facility: NCA 10

  
\_\_\_\_\_  
Date

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

  
\_\_\_\_\_  
TERRY L. SPITTLER  
NETWORK CONTRACT MANAGER  
NETWORK CONTRACTING ACTIVITY 10  
VA HEALTHCARE SYSTEM OF OHIO

  
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Date