

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Activity:**

Department of Veterans Affairs, VISN 02



2. **Nature and/or Description of the Action Being Processed:** VISN 2 Gastroenterology Services in Buffalo, NY is requesting a "brand-name only" purchase for the Barrx Flex Energy Generator and return of (2) used generators intended to be awarded as a new, firm fixed price contract with any supplier who can provide the requested products as manufactured by:

Covidien Sales, LLC dba Barrx
15 Hampshire St
Mansfield, MA, 02048-1113

3. **Description of Supplies/Services Required to Meet the Agency's Needs:**

This acquisition is for the Barrx Flex Energy Generator. Specifically, the contract will include one (1) each of the following equipment:

- a) P/N 1190A-115A- Barrx Flex RFA Energy Generator
- b) P/N FLEXFS-010A- Barrx Flx Footswitch (included with the above)
- c) P/N FLEXCC-020A- Barrx Flex Output Cable (included with the above)
- d) RFA Cart (included with the above)

The total cost of the equipment is estimated to cost [REDACTED] after the trade in of existing Generator in use.

The expected delivery date for the above will be within 30 days of award.

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

- (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):**

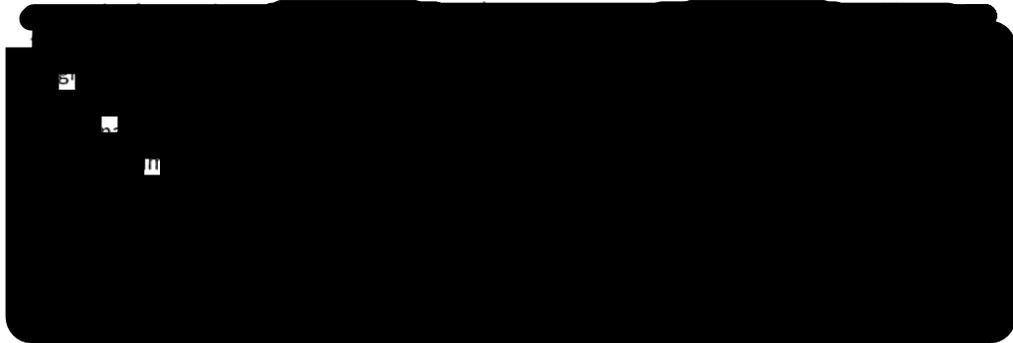
Only the GI Barrx Flexible Energy Generator manufactured by Covidien Sales, LLC can meet the VA's needs. The Barrx Flex RFA Energy Generator is a highly specialized system, which has become the standard system for Radiofrequency Ablation (RFA) procedures. The Buffalo Gastroenterology

Department is intending to replace its currently obsolete Barrx HALO 360 and Barrx HALO 90 RFA generators.

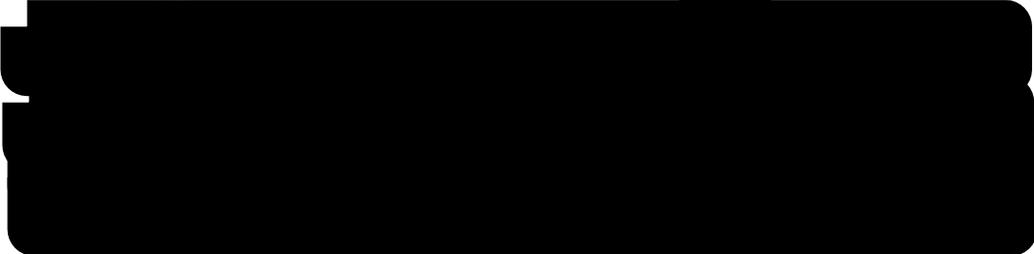
The existing generators were manufactured and supplied by Covidien. The requested replacement is a single generator which provides the same functions as the dual generators as well as utilizes the previous generators' consumables. The Buffalo VA Medical Center is requesting the Barrx Flex RFA Energy Generator which is capable of circumferential esophageal ablation and focal esophageal ablation. The requested RFA Flex Generator also provides intuitive sizing for improved differentiation between the esophagus and stomach. The intuitive sizing automatically recommends ablation catheter sizing, tracks and displays the total number of ablations, and automatically adjusts the default power density settings to match each catheter. Another innovative quality of the requested Barrx Flex RFA Energy Generator is the internal platform it is built upon. The platform was created to uphold future clinical and product innovations from the manufacturer. The total system is activated through a footswitch for hands free activation.

Covidien is the only known FDA approved RFA generator producer. Numerous studies have been done on the RFA method of treating Barretts Esophagus. All of the studies obtained through market research indicate the Barrx System by Covidien as the tool used to execute Radio Frequency Ablation of Barretts Esophagus.

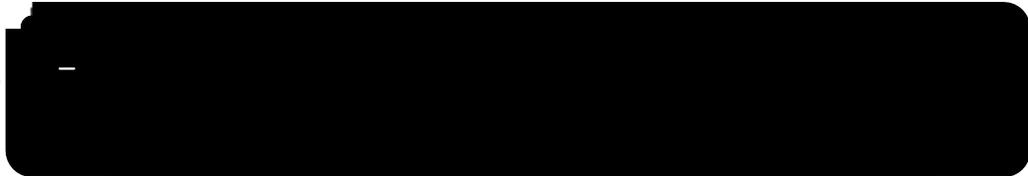
6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

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7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:

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8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:

A large black rectangular redaction box covers the content of item 8.

[REDACTED]

9. Any Other Facts Supporting the Use of Other than Full and Open Competition:

The HALO Coagulation Systems, also known as BARRX after the Barrx Inc. acquisition by Covidien Sales, LLC have received FDA 510(k) clearance: HALO 360 in 2005, the HALO 90 in 2006, and most recently, HALO FLEX in 2009. These devices were approved for use (per the FDA) in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's esophagus, Dieullafoy Lesions, and Angiodysplasiathe. In addition, the HALO FLEX (aka Barrx Flex RFA Energy Generator) is indicated for use for the coagulation of soft tissue.

As the Barrx 360 and Barrx 90 have matured and become obsolete. The Buffalo VA Medical Center has a continued need to support patient requiring such medical treatment, therefore the Barrx Flex RFA Energy Generator is being requested.

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

[REDACTED]

[REDACTED]

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:

[REDACTED]

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.

[Redacted Signature]

3/26/2014
Date

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

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

[Redacted Signature]

[Redacted Signature]

Date

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

[Redacted Signature]

[Redacted Signature]

Date