

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

1. Contracting Activity: Department of Veterans Affairs, NCO 16, VA Gulf Coast Veterans Health Care Systems, Biloxi, MS.

2237 Transaction Number: 520-13-2-9342-0050

2. Nature and/or Description of the Action Being Processed: Purchase of Endo-Surgery equipment to allow the facility the capability to perform laparoscopic colon surgery.

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

Ethicon Endo-Surgery Generator G11 with accessories; Cart G11, Enseal generator connector, Footswitch and harmonic generator connector.

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)

Ethicon is the only distributor of the harmonic/enseal generator (GEN11). All disposable devices that are compatible with the GEN 11 are proprietary to Ethicon. The Enseal generator combines advanced technology, multi-functionality and touch screen simplicity in one compact, easy-to-operate unit that supports current and future ultrasonic and advanced bipolar devices used in colorectal surgical procedures.

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

A combined synopsis will be published on Fed Biz Ops (FBO) with the intent to sole source for brand name only. Posting to FBO will allow any other firm the opportunity to make an offer should they feel they meet the requirements of the solicitation.

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

Fair and Reasonable pricing is expected based on competition. Prices submitted will be based off published price lists. These are commercial items, sold to the government and commercial customers alike. Prices for the government will be based on best customer value.

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

The NAC website, GSA website and general Google searches were conducted with no viable alternate source revealed. A search of Fed biz Ops revealed that two other VAs had either solicited or issued a sources sought for the Ethicon GEN 11 generator. VA Southern Nevada Healthcare System was contacted in reference to their solicitation VA262-13-Q-3993 for the GEN 11 generator and it was found that Ethicon was the only bidder on the solicitation. SAO West, NCO 19, Rocky Mountain Acquisition Center issued a sources sought on 1 August 2012 and Ethicon was the only responsible source. NCO 19 stated that another vendor did inquire to the sources sought but later called back to say that Ethicon only sells to hospitals and that the sale of the generator and accessories would come directly from Ethicon.

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

To date, it is unknown if any other manufacturer has the capability to provide an advanced technology and multi-functionality unit that supports current and future ultrasonic and advanced bipolar devices used in colorectal surgical procedures. Currently, Veterans with malignant diseases are being referred for non-VA care while Veterans with benign conditions are placed on a waiting list.

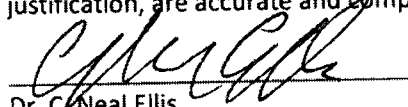
10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

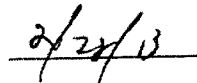
Market research indicated that only Ethicon has responded to solicitations and sources sought by other VAs.

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:

The facility can perform colorectal surgical procedures using traditional techniques, however, it would not be in the best interest of Veterans given the increased morbidity, risk of infection and extended hospital stay.

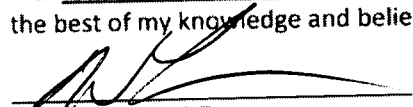
12. Requirements Certification: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.



Dr. C. Neal Ellis
Chief, Surgery Service
VA Gulf Coast Health Care System


Date

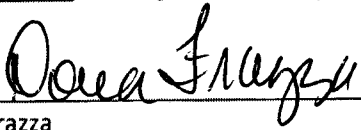
13. Approvals in accordance with FAR 6.304

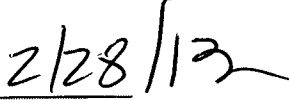
a. Contracting Officer's Certification: (required) I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.


WINDELL LANCE
CONTRACTING OFFICER
NETWORK CONTRACTING OFFICE (NCO)16
VAGCVHCS Biloxi Medical Center, Biloxi, MS


Date

b. **CHIEF P&C:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.





DATE

Donna Frazza
CHIEF, PURCHASING AND CONTRACTING
NETWORK CONTRACTING OFFICE (NCO) 16
VAGCVHCS Biloxi Medical Center, Biloxi, MS