

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA246-15-AP-6854

1. **Contracting Activity:** Department of Veterans Affairs, Network Contracting Office 6, Kernersville Health Care Center. The purchase request number is 659-15-3-930-0186.
2. **Nature and/or Description of the Action Being Processed:** This is a sole source procurement of four (4) ERBE VIO 3000D electrosurgical units, four (4) argon plasma coagulators and related parts, for delivery to the Kernersville Health Care Center in Kernersville, North Carolina. A new firm-fixed price purchase order will be awarded. The independent government estimate is \$[Redacted]. This procurement is being conducted in accordance with FAR Subpart 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. **Description of Supplies/Services Required to Meet the Agency's Needs:** The Kernersville Health Care Center in Kernersville, North Carolina requires the ERBE VIO 3000D electrosurgical units and four (4) APC2 argon plasma coagulators for gastroenterology and endoscopy service. The electrosurgical unit is used for the cutting of tissue and the coagulation of bleeding vessels during surgery. The argon plasma coagulator is an attachment of the electrosurgical unit, and is used for cauterization/coagulation for specific types of procedures.
4. **Statutory Authority Permitting Other than Full and Open Competition:** The authority for applying FAR Subpart 13.5 is (Section 4202 of the Clinger-Cohen Act of 1996) and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2), IAW 41 U.S.C.
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 sole source procurement is being conducted on the basis of (1) standardization with existing equipment used at the Salisbury VA Medical Center and satellite medical facilities. The equipment is familiar to medical staff and changing brands would unnecessarily increase the risk of patient injury, as medical personnel rotate between facilities. (2) Use of another brand is prohibitive due to concerns related to training. The medical staff is trained on the ERBE brand of electrosurgical/APC equipment and must have their competency affirmed on a periodic basis. Using another brand of equipment will cause the facility to revise its training program and to re-establish competency for all users on multiple devices, in different locations. No competing device is so advantageous as to warrant changing brands and causing the facility to conduct multiple, repetitive training actions to support one device. Standardization for the purpose of ensuring patient safety was supported under GAO ruling B-411904. Standardization is further supported in the attached peer-reviewed journal article, "Evaluating and Predicting Patient Safety for Medical Devices with Integral Information Technology."

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Market research has been conducted regarding this procurement.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The price is reasonable when compared to list prices of competing products.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** A sources sought and special notice were issued. Additionally, product literature was reviewed for identified brands.
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:**
Medfinity (DUNS: 148938272), Veterans Healthcare Supply Solutions (DUNS: 964899483)
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 being taken at this time. Market research will be conducted when equipment is reprocured.
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.

//signed//
[Redacted]
Assistant Section Chief of Digestive Diseases
and Endoscopy
Salisbury VA Medical Center

Date

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
Attachment 3: Request for Sole Source Justification Format >\$150K

13. Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP. *This part if filled out by Contracting Staff as part of the Justification*

a. Quality Assurance Coordination (required over \$150k):

<u>//signed//</u>	_____
[Redacted]	Date
Lead Contract Specialist	
NCO 6	

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

<u>//signed//</u>	_____
[Redacted]	Date
Branch Chief, Supply Team 1	
NCO 6	

c. Director of Contracting /Designee (Required \$150K and above): I certify the justification meets requirements for other than full and open competition.

<u>//signed//</u>	_____
[Redacted] (Designee)	Date
NCO 6 Director of Contracting or Designee	

Attachment

Peer Reviewed Article – Evaluating and Predicting Patient Safety for Medical Devices with Integral Information Technology