LIMITED SOURCE JUSTIFICATION
FOR BRAND NAME SPECIFIC AQUISITION
FAR 13.5 TEST PROGRAM FOR CERTAIN COMMERICAL ITEMS

1. Contracting Activity: Department of Veterans Affairs
Strategic Acquisition Center
10300 Spotsylvania Avenue
Suite 400
Fredericksburg, VA 22408

2. Description of Action: The proposed action is a brand name, limited source, firm fixed price, open market award for the exchange of four Olympus America, Inc. EVIS EXERA III Endoscopic Video Processing Systems; CV-190 Video Processors, CLV-190 Light Sources, MAJ-1918 Remote Cable Peripheral Devices 1.8M, for the Endoscopy Clinic at the Jamaica Plain – Boston Veterans Affairs Medical Center (VAMC).

3. Description of the Supplies or Services:
The estimated value of this action is $177,740.40.

An endoscopic video processing system provides detailed and accurate live video images of the gastrointestinal (GI) tract, utilizing an endoscope and a high definition television (HDTV) monitor. Both the endoscope and the HDTV monitor are directly connected to the video processing system. The video processor must be able to send the acquired still and video images of endoscopy procedures to the Olympus Endoworks Image Management System. This compatibility is vital for the endoscopy service workflow, because images and videos could not be properly stored and made accessible without it.

The EVIS EXERA III offers a significant increase in video clarity and resolving power over the existing EVIS EXERA II systems, which results in better clinical outcomes. In addition, the EVIS EXERA III offers a universal platform that is compatible with Olympus flexible and rigid endoscopes across all specialties, including: GI, bronchoscopy, laparoscopy, and ear, nose and throat (ENT). This upgrade will increase and expand the capabilities for each of the procedure rooms in the Boston VAMC.

In accordance with Veteran's Health Administration (VHA) Directive and Handbook 1761.1, Standardization of Supplies and Equipment Procedures, all three medical centers in the VA Boston Healthcare System are standardized to Olympus video processing systems. As an extension of the equipment standardization, VA Boston has existing clinical competencies for the practitioners of the Endoworks system. As such, it is imperative for the GI Department to have the same video processing systems, make and model, in place to establish a baseline for design improvements, install updates, and best workflow practices. The EVIS EXERA III is similar in functionality to the EVIS

EXERA II, which will decrease the amount and cost of training and education required; limiting the learning curve that ultimately impacts patient care. Two (2) EVIS EXERA III video processing systems have been purchased for the Endoscopy clinic through Clinical Engineering Service Transaction #523-12-4-7057-0024. Upgrading the remaining four (4) systems from EVIS EXERA II to EVIS EXERA III will complete the standardization of endoscopic technology throughout the clinic.

4. Rationale for Limiting Competition: There is no express authority for the sole source, or limitation of sources, under FAR Subpart 13.5; this justification fulfills the requirements set forth under FAR Section 13.501, and is in accordance with Section 4202 of the Clinger-Cohen Act of 1996.

Olympus is the proprietary manufacturer of the Endoworks system, which makes Olympus the only vendor that can provide a compatible video processing system. Restricting competition to only those vendors capable of providing the Olympus EVIS EXERA III allows for standardization, compatibility with the information infrastructure, and interoperability with existing equipment (i.e. endoscopes). The Olympus EndoWorks system is compatible with all of the Olympus video processing systems, (i.e. EXERA I, EXERA II, and EXERA III); it is not compatible with other company's video processing systems. As such, the use of descriptions in the acquisition, limiting the acquisition to this peculiar manufacturer, is essential to the Government's requirements; thereby precluding consideration of a product manufactured by another company.

5. Efforts to Obtain Competition: Market research, as discussed in section 7, validated that Olympus America, Inc. is the sole manufacturer of the required items of this acquisition. Additionally, a Sources Sought notice was posted to Federal Business Opportunities (FBO) on April 22, 2013, resulting in the identification of multiple authorized re-sellers of Olympus products. Although true competition cannot be achieved for this requirement, due to the items coming from a sole manufacturer, the original sole source strategy was adjusted to a limited source; the limited source strategy allows for the Government to support small business concerns that are capable of providing the required items.

6. Actions to Increase Competition: In order to remove or overcome barriers to competition in future acquisitions for this requirement, the agency would have to replace the entire system. Therefore, no actions are currently available to increase competition for the specified requirement.

7. Market Research: The initial market research of vendors such as Fujinon, Karl Storz Endoscopy, Pentax, Richard Wolf, Smith and Nephew, and Stryker Endoscopy revealed that most companies have a proprietary relationship between their image management systems and associated video processing units. Discussions with these companies validated the Government's position that only Olympus offers a video processing system compatible with the Olympus Endoworks system utilized at the VA Boston clinic.

A query of Veteran-Owned and Service-Disabled Veteran-Owned Small Businesses in the VetBiz registry IAW the Veterans Benefits, Health Care, and Information Technology Act of 2006, 38 U.S.C. §§ 8127-28 and the VA Acquisition Regulations (VAAR) Part 810.001 was conducted. This mandatory effort was to determine availability of VOSB sources for set-aside procedures. A query of the VetBiz database produced ten potential suppliers under this requirement. Each supplier was contacted by the Strategic Acquisition Center to inquire as to their capability to provide the subject requirement, or an "Or Equal". The findings resulted in no capable suppliers.

The priorities for use of Government supply sources per FAR 8.002(a)(1), Supplies, was reviewed. This review determined that the required items were only available from Commercial sources. It should be noted that the sole manufacturer, Olympus America, Inc. does have a Federal Supply Schedule (V797P-2065D), however the EVIS EXERA III items are not on said schedule. Therefore, procurement from FSS is not an option.

A Sources Sought – Request for Information (RFI) was posted to the Government Point of Entry (GPE), Federal Business Opportunities (FBO), seeking sources under this requirement. The notice was issued April 22, 2013, with a closing date of April 25, 2013. The results of the notice yielded two responses; a SDVOSB and a VOSB. Both respondents provided authorized re-seller letters. The Government and the vendors have validated with Olympus that the requirement can be fulfilled through the authorized resellers.

Additional market research efforts and the findings of such research included, but was not limited to –

- A review of the Thomas Registry (Thomasnet.com), which revealed one source under the EVIS EXERA III product line, Olympus America, Inc.

- A review of the Federal Business Opportunities (FBO) database for previous history data. The FBO database listed six previous buys under this requirement. Of the six announcements posted, there were three awards: one to the manufacturer, Olympus America, supported by a Single-Source J&A, award date: February 5, 2013; one to a SDVOSB, Vetcor USA, award date: February 14, 2013; and one to a Small Business, Butterroot Services & Technology LLC, award date: April 14, 2013. All three awards were based on the Olympus America products.

- A further review of the Internet identified a company named Medwow, which specializes in new and used medical equipment sales. Reviewing the company's product line, the desired EVIS EXERA III was not one of the items listed as one of the products they can provide.

- In accordance with the Federal Drug Administration (FDA) 501(k) findings, dated December 11, 2012, Reference: K123317, which approved the Olympus EVIS EXERA III Gastrointestinal Videoscope System for its intended use, it is to be used with an

Olympus video system center, light source, documentation equipment, monitor, and other ancillary equipment for endoscopy and endoscopic surgery.

8. Other Facts: Not Applicable

9. Interested Sources:
1) (SDVOSB) R & M Government Services Inc., 545 CORONA DEL CAMPO LOOP, LAS CRUCES, NM 88011
2) (VOSB) Executive Career Search, Inc., D.B.A. Miller & Dickey Medical, Inc., 4098 Cardinal Glen Place, Ste. 100, Oviedo, Florida 32765-9251

10. Technical and Requirements Certification: I certify that the supporting data under my cognizance, which are included in this justification, are accurate and complete to the best of my knowledge and belief.

[redacted]

Clinical Engineering Manager
Boston VAMC

[redacted]

Signature: Date: 5/09/2013

11. Contracting Officer Certification: As Contracting Officer, I anticipate the price of this acquisition to be determined fair and reasonable based on price analysis in the form of comparisons with similar items, from the manufacturer's and/or other manufacturer's GSA schedules, for which pricing has previously been determined fair and reasonable by a Contracting Officer.

I certify that this justification is accurate and complete to the best of my knowledge and belief.

[redacted]

Contracting Officer

Date: June 11, 2013

Signature: [redacted]