

**DEPARTMENT OF VETERANS AFFAIRS**

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

**KARL ZEISS BRAND NAME ONLY VISUAL FIELD ANALYZER SYSTEM**

**Acquisition Plan Action ID:** VA256-18-AP-4193

1. **Contracting Activity:** Department of Veterans Affairs, Network Contracting Office 16, VISN 16, Veterans Health Care System of the Ozarks, Fayetteville, AR  
Purchase Request (2237) Number: 564-18-2-1099-0015

2. **Nature and/or Description of the Action Being Processed:**

This procurement is for a Karl Zeiss brand name Visual Field Analyzer System for use in the Eye Clinic at the Springfield, Mo Community Based Outpatient Clinic in Springfield, MO in accordance with FAR 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.

This is a new requirement and will be pursued as a Firm Fixed Price contract on the open market for Brand Name Only competition.

The estimated value of this procurement is [REDACTED] The estimated award date is [REDACTED]

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

The following equipment is required to equip Optometry Exam Rooms at a new activation, Veterans Health Care System of the Ozarks (VHSO), Springfield, MO Community Based Outpatient Clinic. This same equipment is used consistently in the VHSO Eye Clinics at Fayetteville, AR, Branson, MO and Mt Vernon, MO. The procurement of this equipment will allow for a seamless transition of providers from one clinic to another and allows for continuity of care when patients are examined at multiple clinics.

**REQUIRED EQUIPMENT:**

1. Co-observation tube ("teaching tube" attachment to slit lamp), QTY: 1
2. Atlas 9000 (Corneal topographer), QTY: 1
3. HFA3 Model 860 (Visual Field System-Humphrey), QTY: 1
4. K2 table (power table for instruments – visual field), QTY: 2
5. SL 130 (slit lamp), QTY: 9
6. Matrix 800 (Visual Field System-Matrix), QTY: 1

The estimated total cost of this requirement is \$157,816.00.

Delivery is required no later than 30 May 2018.

**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 13.106-1(b)(2);
- ( ) (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;

**FAR13.5 Simplified Procedures for Certain Commercial Items:** The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).

**5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**

This is a procurement for Brand Name Only competition.

The Veterans Health Care System of the Ozarks located in Fayetteville, AR has the need for one Visual Field Analyzer System. Carl Zeiss Meditec, Inc. is the only manufacturer of the Humphrey Field Analyzer 3 (HFA 3). The Zeiss HFA 3 is an automated perimetry system used in the diagnosis and management of disorders affecting the optic nerve, retina, and visual pathway. The HFA 3 is also the only device that will provide continuity with the current Zeiss HFA II-I units, which are currently used in the Health Center's eye clinics. These instruments include software that provides a sophisticated analysis of disease progression based on comparison with historical data. The purchase of the HFA 3 ensures compatibility with current technology for reliable patient data transfer, thereby enabling the VA to continue to generate useful clinical data. Additionally, all providers are trained on the use and interpretation of results generated by this instrument. The Zeiss HFA 3 is also approved as DICOM-compatible for networking.

Zeiss is the only unit with a magnification setting of 32, which is ideal for evaluation of certain structures of the eye including the anterior chamber.

The Zeiss SL 130 was compared to Haag-Streit BM 900 LED, Reichert XCEL 455, and Topcon SL-D701. Zeiss is the only model with top-mounted applanation tonometers. The other models each have side-mounted tonometers which have disadvantages including decreased stability and therefore decreased repeatability and accuracy.

Zeiss is the only model with a quick-lever locking mechanism in addition to the screw-type locking system, whereas the other models are limited to only the screw-type. The quick-lever mechanism allows for instant instrument and light source stability, which is critical for certain examination techniques and procedures.

Zeiss is the only model with light source adjustment dials all consolidated on the light housing; the other models have some controls on the light housing and others on the top mounting. Consolidated controls allow for increased efficiency and provides increased safety during procedures.

We have equipped each of our exam rooms at each of our sites with identical equipment to maximize efficiency, allowing our providers to move seamlessly from room to room and from clinic to clinic. Zeiss is the only manufacturer that is compatible with our existing equipment, infrastructure, and supplies. Standardization of equipment is considered a strong action to prevent errors and promote patient safety. Standardization of equipment allows for streamlined reprocessing. It also assists both the end user and Sterile Processing Services in training and re-ordering.

The Carl Zeiss Meditec, Inc. Humphrey Field Analyzer 3 provides a glaucoma progression analysis that helps monitor rates and reliability of progression data, allowing continued direct comparison to past fields for progression analysis. If the facility were to use a different brand, it would need to re-establish baseline field testing for every glaucoma suspect and patient. Clinical studies suggest that at least 6 visual fields are needed to establish a baseline. The reports generated by other brands may differ in many ways and therefore do not allow for direct comparison for co-managed patients. It is critical that the facility be able to communicate with the same test and reports for co-managed patients.

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

A sources sought synopsis, Number 36C25618Q9230m was issued, for a Karl Zeiss Visual Field System for use at the Springfield Community Based Outpatient Clinic in Springfield, MO. Two (2) responses were received from SDVOSBs. The CO determined from the results of the screening process that the two respondents were capable of providing the brand name requirement equipment.

The Rule of Two does not exist for Veteran-Owned Small Businesses (VOSBs) or Service-Disabled Veteran-Owned Small Businesses (SDVOSBs). Previous procurements have shown this equipment to be available from the manufacturer and at least two small businesses. The Contracting Officer confirmed that both small businesses are authorized to resell Keiss equipment and normal manufacturer warranties will flow-down the Government. The equipment is not available on a contract vehicle other than the open market.

It is determined that this procurement be set-aside for small business, brand name only request for quotation on the open market IAW FAR 13.106-1.

The CO received only three (3) expressions of interest received] responses, which are:

Name of Offeror	Name and Address of Building
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

**7. Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** Competition will determine a fair and reasonable cost.

**8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons**

**Market Research Was Not Conducted:** In order to meet the VA Rule of Two, The COs reviewed the Vendor Information Pages (VIP) database in accordance with VAAR Class Deviation 810.001-70 to determine if two or more service-disabled veteran-owned businesses (SDVOSBs) and veteran-owned small businesses (VOSBs), in NAICS code 334510, were listed as verified in the VIP database. The query returned 55 matches SDVOSB/VOSBs. However, the Rule of Two does not exist for Veteran-Owned Small Businesses (VOSBs) or Service-Disabled Veteran-Owned Small Businesses (SDVOSBs) for this requirement. Zeiss, a large business, is the sole manufacturer of the required products.

In addition, previous procurements have shown this equipment to be available from the manufacturer and at least two small businesses.

Market research was conducted, details of which are in section 8 of this justification. It was determined that limited competition is viable among resellers for these brand name items. In accordance with FAR 5.301 and 16.505(b)(2), this action will be synopsisized at award on the Federal Business Opportunities Page (FBO) and the justification will be made publicly available.

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

Zeiss or an authorized re-sell of Zeiss products are the only known sources that can meet the VA requirement.

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

A sources sought synopsis, Number 36C25618Q9230m was issued, for a Karl Zeiss Visual Field System for use at the Springfield Community Based Outpatient Clinic in Springfield, MO. Two (2) responses were received from SDVOSBs

Name of Offeror
[REDACTED]
[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:**

The Government will continue to conduct market research by continually reviewing competing software products to learn if there have been any changes in the marketplace that would enable future actions to be competed.

**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.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_

**13. Approvals in accordance with the [VHAPM Part 806.3 OFOC SOP](#):**

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

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

- b. **One Level Above the Contracting Officer (Required over\$150K but not exceeding \$700K)**: I certify the justification meets requirements for other than full and open competition.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_