

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, VISN 6, Network Contracting Office, VA Medical Center, Durham, North Carolina. The 2237 number is 558-14-1-122-0025
2. **Nature and/or Description of the Action Being Processed:** BRAND NAME (Zeiss Cirrus HD 5000) -- Approval to limit competition to an item peculiar to one manufacturer in accordance with FAR 13.106-1(b) and 6.302-1(d). Award will be firm fixed price.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** This instrument is used to perform real-time spectral domain, exquisite micrometer resolution with 3D and 2D cross-sectional tomographic images of the posterior segment of the eyes. It tracks progressive retinal nerve fiber layer loss for enhanced glaucoma management.
 - a) Zeiss Cirrus HD 5000 w/FASTTRAC
 - b) The estimated dollar amount is \$77,950.00
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):**

The Zeiss Cirrus HD-OCT instrument possesses the following unique and essential features that justify brand name justification and warrant the usage of authority granted in FAR 6.3021-1:

- The CIRRUS HD-OCT 5000 has been optimized for advanced care with new FastTrac retinal tracking that enables the highest resolution B-Scans to be captured in identical locations from visit to visit providing accurate assessment of change in targeted pathologies which has a twofold purpose.
 - While the OCT scan is being done, the independent system is tracking the retina should the patient move or blink; this is taken care of, corrected, or re-scanned so that there is no motion artifact in the final image. This is particularly essential for patients who find it difficult to fixate.
 - Secondly, if you possess scans of different visits, you can position the HD high-resolution raster scan in exactly the same position so that you can better track the progression of the disease."
- FastTrac compensates for eye motion during scanning and can be optionally turned on to assist with poor fixators to optimize patient throughput.

- Additionally, to meet the needs of advanced care, the CIRRUS HD-OCT 5000 is configured with the highest resolution visualization capabilities and sophisticated applications, such as Advanced RPE Analysis to track retinal pigment epithelial integrity, and Ganglion Cell Analysis to assess glaucomatous loss in the macula that may not be evident in the peripapillary region

Accordingly, Carl Zeiss is the only firm capable of manufacturing the Cirrus OCT diagnostic instrument described in Section III above without the Veteran's Health Administration experiencing substantial duplication of cost that could not be expected to be recovered through competition and unacceptable delays in fulfilling requirements.

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

Research was conducted to determine the basis of previous awards for the same or similar items. Based on historical data obtained from both FBO and FPDS, the previous awards (i.e. VA528-13-P-2125, and VA250-13-P-1992) were each set aside for small business award. In each instance Metro Medical was the only small business to respond. Sources Sought Notices posted in the past confirmed that other sources are not available to meet the needs of this requirement.

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

The anticipated cost to the government will be determined fair and reasonable through competition solicited via posting on Fed Bid Ops. ?

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

Market research has been done by the requesting service in accordance with FAR Part 10, to identify sources capable of meeting VISN6 patient care requirements. Additional research revealed a very small market for the commodity identified in Section III. A Sources Sought Notice was published to the FBO to identify small business sources capable of supplying the items described in Section III, and only one small business entity, Metro Medical, responded.

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

Existing Zeiss OCT machines that are outdated can be traded in; the trade in amounts can be applied to new purchases. The value of these trade-in units are approximately \$10,000. The usage of Carl Zeiss HD-OCT instruments will facilitate the trade-in process and will reduce the overall price by the Government in meeting VISN6 patient care requirements.

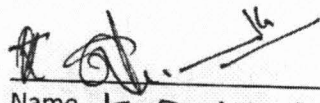
10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

Metro Medical

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:

Available actions to be taken are limited due to the narrow field of competition inherent in the HD-OCT instrument market.

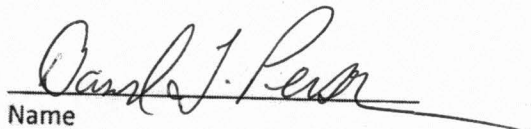
12. **Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge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


Name KURUVILLA P. KURIAN
Title ADMINISTRATIVE OFFICER
Facility DURHAM VAMC

12/19/13
Date

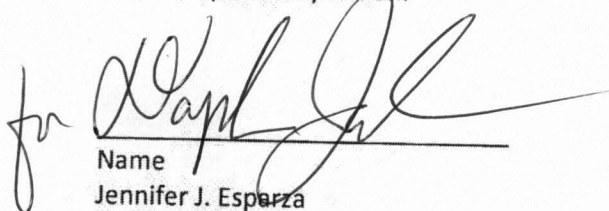
13. **Approvals in accordance with FAR 6.304**

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


Name
Title
Facility

12/24/13
Date

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

for 
Name
Jennifer J. Esparza
Commodities Team
NCO-6

12-24-13
Date