

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, NCO 23, St. Cloud VA Healthcare System, 4801 Veterans Drive St. Cloud, MN 56303, 618-14-3-040-0564. This is a justification for other than full and open competition.
2. **Nature and/or Description of the Action Being Processed:** Firm fixed price purchase order for an upgrade to the existing IOL Master Unit from Metro Medical Equipment & Supply Inc. at the Minneapolis VA Health Care System.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** IOL Master is an automatic cataract biometry system that does not make contact with the patient's eye with precision for optimal reflective outcomes. It is a non-contact optical device that measures the distance from the corneal vertex to the retinal pigment epithelium by partial coherence interferometry, used in clinical ophthalmology. The unit has an internal algorithm that approximates the distance to the vitreoretinal interface and allows fast, accurate measurements of eye length and surface curvature, necessary for cataract surgery. It also measures axial length, anterior chamber depth, lens thickness, pachymetry and retinal thickness of the eye. There is no need for anesthesia and no potential for spread of contamination, because the IOL Master is non-contact (nothing touches the eye itself).

The upgraded software will contain the additional Holladay II formulas inside the unit, eliminating the need to transfer data to an external computer. Holladay II formulas allow for the calculations with a broader range of axial lengths and central corneal powers. Holladay II formulas use several additional variables, instead of just two variables, to adjust IOL power such as horizontal corneal diameter, lens thickness, anterior chamber depth, age and preoperative refraction.

Other items needed to meet our need is a table to set the device on and a printer to print documentation from the device for clinical review. Additionally, the upgrade should contain a Sonolink connection, so that the data transfers to and from the IOL Master and the existing Accutome A-Scan Synergy ultrasound device.

Estimated Dollar Value: [REDACTED]

Required Delivery Date: 6/20/2014

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):** Carl Zeiss is the manufacture of the existing IOL Master unit and the requested upgrade at the MVAHCS. Metro Medical, a Small Disadvantage Business, is the sole distributor for manufacturer, Carl Zeiss Meditec, Inc. The current system interfaces with our existing Merge Optical Image Management System. Our biomed technicians and clinicians have already been trained on using the conducting preventative maintenance on the current device. It would be more expensive to by a whole new biometry system than it is to purchase the upgrade, based on reviewing catalogs and other product literature available online

published by manufacturers such as Nidek and Haag Streit. If another device was selected we would also need to purchase clinical and biomed school training for the biomed technicians and clinicians incurring additional costs beyond the software upgrade.

- 6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** The upgrade is for the existing MVAHCS IOL Master Unit and is not available on GSA or any other sources based on internet search. Carl Zeiss Meditec, Inc is the parent company and original manufacturer, while Metro Medical is a Small Disadvantage Business and the sole distributor for Carl Zeiss Meditec, Inc.
- 7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The Contracting Officer will determine the price to be fair and reasonable.
- 8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** The upgrade to the existing MVAHCS IOL Master Unit is not available on GSA or any other sources based on internet search. Carl Zeiss Meditec, Inc is the parent company and original manufacturer of the existing MVAHCS IOL Master Unit. Metro Medical is a Small Disadvantage Business and sole distributor for Carl Zeiss Meditec, Inc.

Market research was conducted using Google and looking at manufacture websites like Nidek and Haag Streit that offer similar products, but do not meet our feature and compatibility requirements. Also, looked on government databases for similar agency acquisitions and found several on fedbizopps like solicitation number VA246-13-Q-0143_01, VA250-13-Q-0935 and FM480012707005.

- 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:** None
- 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:** If in the future these items are needed, the requesting service will perform market research to see if additional products can be found to compete this requirement.
- 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.

[Redacted Signature]

Biomedical Engineer - MVAHCS

5/5/2014
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.

[Redacted Signature]

Contracting Officer, NCO 23 – St. Cloud

5/5/2014
Date

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

[Redacted Signature]

Product Line Contract Manager, NCO 23 – St. Cloud

5 MAY 14
Date