

DEPARTMENT OF VETERANS AFFAIRS

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

1. **Contracting Activity:** Department of Veterans Affairs, VISN 11, John D. Dingell Medical Center, 4646 John R Street, Detroit, MI. Transaction #553-15-4-063-0102

2. **Nature and/or Description of the Action Being Processed:** Award of a firm-fixed price purchase order to "ProAim America, LLC" Company.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The Ophthalmology department is requesting the purchase of two (2) Zeiss Cirrus HD OCT Model 5000 and two (2) Anterior segment Premier Module at a cost of \$158,795.00. The estimated delivery date needs to be ASAP due to the manufacturer no longer supporting the old OCT system. These new units are needed to provide services to veterans while maintaining the high standard of care.

4. **Statutory Authority Permitting Other than Full and Open Competition:** *41 USC §3304(a)(1), as implemented by FAR 6.302-1.*
 - (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;

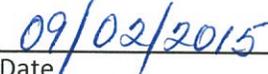
5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** This is a "Brand Name Justification." Only the manufacturer "Carl Zeiss" can produce these products. The eye clinic utilizes a variety of equipment, due to the complexity of this equipment, are requesting Zeiss equipment. The Zeiss Cirrus HD-OCT Model 5000 equipment is compatible with existing Zeiss units, being able to communicate and transfer data from one unit to another, and are already configured and networked to our databases. Our VA population has a high prevalence of Glaucoma and retinal disease. This instrument significantly improves the ability of the clinicians to make appropriate treatment decisions involving glaucoma and retinal disease as well as the need for surgeries. The current OCT 4000 is through Carl Zeiss and has been used to capture patient's clinical information

and images for diagnostic purposes for the past 5 years. The Cirrus HD-OCT Model 5000 unit has the ability to import and integrate the Cirrus Model HD 4000 'raw data', obtained over the past five years, currently being used at this medical center. The raw data must be interchangeable and compatible between the Cirrus 4000 and Cirrus 5000 unit. This allows the clinic to import the patients' data from the Cirrus 4000 and incorporate it into the Cirrus 5000, which allows for continuity and precise progression data management, if not, all data from the Cirrus 4000 becomes only a static report in PDF format that cannot be built upon. Historical data will be useless and it will be necessary to start new baseline data. Currently, we have greater than 5 years of patient data which needs to be integrated into the new machine. Having this data and integrating onto the new machine allows providers to assess progression or resolution of disease states. Assessing progression helps to determine treatment necessity as well as aggressiveness of the treatment. The unit must be able to 'track' to prior scans and assess the same area of the nerve fiber layer and macula as previous scans. It will be necessary to upload current patient's data and images to the new OCT for continuity of care for our veterans. The new OCT must be compatible to receive the past 5 years of patient's information and imaging so there is no conflict with the interpretation of patient's information. The Carl Zeiss machine is able to run Guided Progression Analysis of the optic nerve or Macular Change analysis utilizing the historical data from Zeiss Cirrus in a report. This unit is able to 'track' to prior scans and assess the same area of the nerve fiber layer and macula as previous scans. Maintaining the same vendor will allow a smooth transfer of patient's information, images and eliminate the potential for interface miscommunication between the old and the new equipment. The biomedical engineering department has a parts inventory dedicated to the Zeiss OCT current units which are interchangeable with the new Cirrus HD OCT Model 5000. This inventory will minimize equipment downtime, clinical impact, and biomedical techs are trained to work on these units. Accordingly, ProAim Americas LLC is the only firm capable of providing the supplies 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 its requirements.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Only one manufacturer "Carl Zeiss" and one distributor "ProAim Americas LLC" was noted at the time of research that carries the equipment that is able to interface with the current equipment needed for diagnostic and imaging requirement of the Ophthalmology department. ProAim Americas LLC meets the clinical requirement of the patients and alternative equipment may put the patient community at risk. The Ophthalmology department and the surgeons request not to have another vendor's equipment to confuse the users with incompatibility.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated cost is considered fair and reasonable as this is the same historical price paid by other facilities for the same or similar equipment.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research was conducted GSA Advantage and Google shows Zeiss Cirrus Model 5000 is the only equipment that has the ability to integrate the data into the current system and also that met the needs of the veterans at the Detroit VA. The Optovue machine, by Medfinity Avanti, cannot 'track' to prior scans and assess the same area of the nerve fiber layer and macula from historical scans or run Guided Progression Analysis of the optic nerve or Macular Change analysis utilizing the historical data from Zeiss Cirrus in a report.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** The rationale of choosing the Carl Zeiss unit was the compatibility of the data and image transfer and user familiarity of the equipment. Our current OCT software runs on windows XP. This year, Carl Zeiss will no longer service systems using XP, but only Windows 7. The Clinic's machine will be obsolete and no software upgrades are possible due to the old processors. The requested OCT new machine operates on Windows 7. In addition, there is a greater amount of clinical information gathering with the new equipment which will improve diagnostic capabilities, and the processing speed is much faster, allowing an increased number of patient's evaluations to take place. This improvement in the efficiency of the CIRRUS OCT 5000 is based on the increased processing speed of patient testing. Shorter testing time will allow more patients to be evaluated. There will be cost savings to the medical center. Because the Ophthalmology clinic has a large patient population with glaucoma and retinal diseases, demand is high for the use of this diagnostic instrument. The clinic will continue to be able to service veterans within the facility, with our instruments, and not fee base patients to community providers for these tests.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** ProAim Americas LLC, 209 Bountiful Pointe Circle, Wildwood, MO 63040-2126, contact person: Shannon Brown 844-467-7624.
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** There are no other interested sources other than the manufacturer that can provide the same product required to interface with the existing data and imaging. When this equipment is replaced again the market will be surveyed in order to identify the multiple prospective vendors. There are no known barriers to competition.
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.


Susan Tyler-Davis, MHSA
Administrative Officer, Surgical Service
John D. Dingell VAMC, Detroit, MI


Date

13. Approvals in accordance with the

- 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 Joyce Miller

Date

Title

Facility Department of Veterans Affairs

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

Name James J. Hallock

Date

NCO/PCO Supervisory Contract Specialist

Facility Department of Veterans Affairs