

**DEPARTMENT OF VETERANS AFFAIRS**  
**Justification and Approval**  
**For**  
**Other Than Full and Open Competition**

**1. Contracting Activity:** Department of Veterans Affairs, VISN 08, Bay Pines VA Medical Center 516

This is a request for a Sole Source Justification.

**2. Nature and/or Description of the Action Being Processed:** This action is to procure 4 Centurion Vision systems and 18 centurion Ozil hand pieces for use in the operation room in the main OR at Bay Pines and in Cape Coral CBOC from the original equipment manufacturer (OEM) – Alcon via Sole Source. Alcon Laboratories is the sole manufacturer and distributor of the centurion vision system. Only the centurion vision system incorporates technologies that are required by our facility and each is propriety to the centurion vision system.

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

Item #	Description/Part Number*	Qty
1	8065751763/Centurion Vision System	4
2	8065751761/Centurion Ozil HP	18

**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 Ophthalmology department has demonstrated this particular system and it is backwards compatible with the current hand pieces that our facility currently owns. We must have these units as they are compatible with some of the existing hand pieces we currently own thus allowing us not to have to purchase duplicate equipment from another manufacturer. We have owned and operated Alcon in the past with a positive performance and service history. Alcon is the original equipment manufacturer of the Centurion Vision System and Ozil hand pieces. This is a proprietary system that is only manufactured and distributed by Alcon. Active fluidics provides fluidics during active phacoemulsification. Active fluidics is necessary because it allows the surgeon to operate at a targeted intraocular pressure (IOP) which is essential for at least 30% or more of our patients with glaucoma and optic nerve damage. The Centurion is the only system on the market that has this active fluidics system. Fluidic system shall respond quicker than gravity-fed or pressurized irrigation system. The system shall be compatible with the Zeiss and Leica microscopes that are already in use by the medical centers. This allows for controlled implantation of the intraocular lens (IOL). This Centurion Vision System is the only system that has this feature.

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

Alcon is not on Prime Vendor and is not on GSA. Alcon is the OEM and does not distribute.

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

Bay Pines VAMC currently has 2 Alcon Cataract Infiniti units and Lee County has one unit. Bay Pines units were purchased in 2004 at a cost of approximately \$58,000.00 each and Lee County's unit was purchased approximately one year ago but never used due to physician unavailability. The purchase price for four (4) new units and 18 hand pieces is a total of \$277,993.36. This makes each of the four (4) Centurion Units \$60,498.34 and the hand pieces \$2,000.00. I have determined that the price is fair and reasonable based on the fact that in 10 years the new and improved Centurion Units have only gone up approximately \$2,000.00 each.

**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 by Dr. Culotta and it was determined that no other cataract unit can meet the specifications that the Alcon Centurion Vision System. We examined three other cataract units on the market and they do not meet the specifications for the types of cataract surgeries we perform at Bay Pines and Lee County VAMC.

- 1) Abbott Medical Optics- CATALYS Precision Laser System is "Designed for Laser Cataract Surgery" which requires a Femtosecond laser.
- 2) Microsurgical Systems- Bausch + Lomb's Stellaris Vision Enhancement System is used only with 1.8 mm micro incision cataract surgery (MICS) – which we do not perform here (our wounds are like most ophthalmologists wounds (2.6-2.7mm) and this micro surgery through a 1.8 mm incision requires multiple different instruments that fit through this smaller wound as well as a significant learning curve for the surgeon to perform the surgery through this smaller wound.
- 3) OPTIWAVE REFRACTIVE ANALYSIS System (ORA) - With the ORA System, WaveTec is intraoperative wave front analysis to calculate IOL (lens) power – used mainly for premium or toric IOL selection - which we are not using either of these lens types at either of our 2 institutions and it is used for performing LRI's- which are cuts on the cornea for astigmatism.

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

Alcon is the OEM and does not distribute.

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

*Alcon Laboratories*

**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: Tina Culotta-Glynn, DO  
Title: Ophthalmology, Section Chief  
Facility: Bay Pines VAHCS

Date: 4/14/14

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

Contracting Officer  
Facility

Date 4/14/14

Name \_\_\_\_\_  
Contracting Supervisor \_\_\_\_\_  
Facility \_\_\_\_\_

4/14/14  
Date

MITCHELL  
J. THOMAS  
132545

**Mitchell Thomas**  
**Network Contract Manager**  
**VISN 8**

Digitally signed by MITCHELL J.  
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