

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VAA244-16-AP-3628

- 1. Contracting Activity:** Department of Veterans Affairs, NC04, VA Pittsburgh Healthcare System, H.J. Heinz Medical Center. 2237# 595-16-2-480-0025
- 2. Nature and/or Description of the Action Being Processed:** Award of a new Firm Fixed Price Contract to PROAIM America, LLC (sole authorized re-seller to the Government for Zeiss).

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for the award of a Contract, in accordance with FAR Part 13.5 Simplified Acquisition Procedures for certain commercial items.

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

Zeiss OPMI Lumera 700 Microscope and ancillary equipment (See list of items below):

Base Microscope Unit Description:

OPMI® Lumera 700 with magnetic clutches, XYcoupling,integrated beam splitter, with deselectable integrated assistant scope with motorized Zoom (selectable linked or independent assistant zoom) or alternatively manual magnification changer, Superlux Eye Xenon light source with integrated HaMode filter or halogen or LED light source, SCI-Stereo coaxial illumination, motorized zoom (range 1:6), motorized focus and fast focus functionality, depth of focus management system DeepView, binocular tubes, widefield eyepieces, apochromatic objective lens and asepsis with 5.7" GUI touchscreen, wireless or wired 14 function foot control panel.

Part Number/Description	Qty
305953-9900-000: OPMI Lumera 700 Microscope on Floorstand (w/o illumination unit)	1
000000-1776-227: Consisting of OPMI Lumera 700 with magnetic clutches; see quote for additional information.	1
302681-9100-000: Assistant Microscope w/Electrical Zoom For OPMI Lumera 700	1
302681-9023-000: Sci Illumination for Main & Asst. Scope w/o Slit	1
302681-9160-000: Keratoscope	1
304977-9023-000: Superlux 180 Eye Future	1
304970-9020-000: Foot Control Panel Wireless (Fcp WI)	1
304970-8730-000: 3m long cable for wired foot pedal	1
303797-9140-000: Tilttable Tube 110A Motorized Inverter E	2

305810-9001-000: 22mm asepsis caps, pack of 6	8
305542-0000-000: Widefield, Push-In Eyepiece 10X	4
302651-9905-000: Objective F=175 Apo	1
305810-9017-000: 6 pack Asepsis Caps Lumera 700	2
000000-1055-278: Dust Cover for OPMI Blue	1
302681-9740-000: Integrated HD Camera	1
305989-8764-000: Hd-Sdi-Videocable 750hm 2Xbnc Stift 10M	2
309438-9002-000: Trnsprt Case OPMI Lumera 700 Floor Stand	1

The total estimated price is \$157,232.48. The estimated delivery is prior to 4/1/2016.

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):

It is essential the Government's needs that it purchase the Zeiss OPMI Lumera 700 Microscope equipment, since according to PROAIM (sole authorized re-seller to the Government for surgical microscopes for Carl Zeiss Company), the equipment has the following features, they believe is unique to the Zeiss manufactured brand, and not available in another company's similar surgical microscope platform (e.g., not found in any competing ophthalmic surgery microscopy offering in its price category. (See email from PROIM, dated 4/19/16 with attached list of features that are unique to the above referenced equipment, in the PR-IFCAP Action Briefcase).

Additionally, the Lebanon VA Medical Center presently owns a highly specialized, ceiling mounted Zeiss OPMI Lumera 700 microscope. This instrument is interchangeable with the Zeiss Lumera 700 Microscope equipment referenced under #3 above, which is essential to the government, especially if an emergency arises. Zeiss has confirmed that no other manufactures microscope can be interchanged with, or is compatible with, the above mentioned existing ceiling mounted Zeiss OPMI Lumera 700 microscope equipment. (See email from Zeiss, dated 5/10/16), in the Procurement Action Briefcase).

Features Unique to the Zeiss equipment described under #3 above:

Features & Specifications	Standard / Optional	Lock-Out Spec	Sole Source Justification
OPTICS			
Apochromatic optics	S	√	ZEISS apochromatic optics eliminates spherical and chromatic aberrations, providing unparalleled optical clarity, depth of field and color accuracy.
ILLUMINATION			
Superlux® Eye 180 W Xenon light source with HaMode and Retinal Protection Filters.	S	√	Superlux® Eye 180W illumination offers ophthalmic surgeons a whiter, higher contrast, and more natural image of the surgical field than standard halogen illumination commonplace in ophthalmic surgery. Also has foot-pedal activated HaMode filter (mimics Halogen lighting) and a Retinal Protection filter.
SCI™ (Stereo Coaxial Illumination)	S	√	Patented Carl Zeiss technology that splits the illumination such that it travels down a path parallel to the sightline of each eye, resulting in a brilliant, high-contrast and homogenous red reflex for optimal anterior segment visualization.
SYSTEM SETUP			
Invertertube™ E tiltable binocular tube with motorized inverters	S	√	Unique tiltable binocular tube design that incorporates a built-in, motorized optical inverter, enabling the surgeon to activate the inverters via the programmable handgrips or hands-free via the foot control panel.
RESIGHT® non-contact fundus viewing system	O (Existing)	√	A unique Carl Zeiss offering, the RESIGHT non-contact fundus viewing system with sterilizable 60D and 128D aspheric lenses enables the surgeon to switch between the two lenses during a procedure based on preference of magnification, field-of-view and depth-of-field. A built-in, motorized Varioskop lens controllable from the wireless foot control panel enables focusing of the viewing system without changing the distance between the system and the eye, removing the possibility that the system could contact the patient.
Automated transitioning between microscope setup profiles that parallel surgical workflow	S	√	When equipped with the Invertertube E with motorized inverters and the RESIGHT 700 non-contact fundus viewing system, the OPMI LUMERA 700 be configured such that activation of the RESIGHT automatically results in activation of the inverters and any affiliated user profile settings (light intensity, starting zoom and focus values, etc.) to speed transitioning of the microscope between a setup optimal for anterior segment viewing and one for posterior segment.
DeepView	S	√	A depth-of-field management system that allows the surgeon to, at the push of a button, choose between optimized depth perception at all magnification levels or maximum light transmission.
CALLISTO eye® Computer-Assisted Cataract Surgery intraoperative toric	O	√	A unique ZEISS offering, CALLISTO eye is a system that receives biometry and keratometry information from the ZEISS IOLMaster® biometer and uses it to project overlays into the eyepieces of the OPMI LUMERA® family of surgical

alignment system

microscopes in a heads-up-display-like fashion. These overlays increase the accuracy and precision of incision placement, the tearing of the capsulorhexis as well as the centration and alignment of IOLs during a cataract surgical procedure.

VIDEO

DOCUMENTATION

Integrated 1- or 3-CCD HD video camera w/ optional HD video recording on USB-media	3-CCDHD S	√	Unlike other microscopy systems that tout "integrated video," the OPMI LUMERA 700 offers true integrated video. The integrated video cameras and recording and all associated cabling are all fully internalized into the system (no exposed wiring). Furthermore, unlike other integrated video solutions, all video functionality in the OPMI LUMERA 700 are controllable from the central user interface, handgrips or wireless foot control panel – not from a separate camera control unit – offering seamless transition between video capture and other microscope functions.
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SERVICE

Factory trained and certified, regionally located Field Service Engineers	S	√	Unlike other microscope manufacturers, Carl Zeiss services its microscopes only with dedicated, factory trained and certified Field Service Engineers. No contracted 3 rd party service. No sales people serving as service guys. Dedicated ZEISS service located regionally so that they can be onsite quickly to ensure maximum system uptime.
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Only one responsible source:

PROAIM is the sole exclusive seller to the Government for Carl Zeiss Company, for surgical microscopes. (See Zeiss Sole Source Letter, that states PROAIM is the sole seller of Zeiss Equipment to the VA Medical Centers, as well as, the email from Zeiss, date 5/10/2016, confirming PROAIM is the sole exclusive seller of Zeiss microscope equipment. Also see emails from PROAIM, dated 4/14/2106 and 4/22/2016, indicating they are the sole distributor for Zeiss Equipment).

- 6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A Special Notice of Intent to Sole Source Synopsis, including Brand Name purchase and sole seller claims, was posted to FedBizopps for 3 days, and there were no responses.
- 7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The prices Quoted by PROAIM under their updated Quote# L5136624, for each item, is less than the price the VA Nashville, TN Facility paid, under VA Contract# VA249-15-P-4123, for the same items, therefore the price is considered fair and reasonable.

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

A Google Search was conducted using the words “Zeiss OPMI Lumera 700 Microscope” and only Zeiss and PROAIM related links were found.

A GSA Advantage search was done using Zeiss OPMI Lumera 700, and Product No. 305953-9900, and no matches were found.

A Search of the VIP Data Base revealed no matches.

The Requiring Activity performed the following searches: Searches were performed on GSA Advantage Online Shopping and through the NAC website (MedSurg Catalog Search). Some of the accessories were identified, but not the primary microscope. Internet searches also revealed published product comparison information composed by subject matter experts at other VA facilities.

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

The equipment being purchased establishes uniformity within the Lebanon VA Medical Center. Purchasing a different brand or model would interfere with patient safety and require a substantial increase in cost/time involved with training providers to utilize the additional instruments, all of which would not be recovered through competition.

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition: PROAIM who is the sole seller/distributor for Carl Zeiss Meditec to the Federal Government, provided an informal price quotation.

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:

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: Carl Reese
Title: M.D. Associate Chief of Staff for Surgery
Facility: Lebanon VA Medical Center

Date

13. Approvals in accordance with the [VHAPM, Volume 6, Chapter VI: 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.

Name: Ronald Mazzei

Date

Title: Contract Specialist/Contracting Officer

Facility: H.J. Heinz

- b. **Director of Contracting /Designee (Required over\$150K but not exceeding \$700K)**: I certify the justification meets requirements for other than full and open competition.

Name: Elizabeth R. Morin

Date

Branch Chief Commodities Team

Facility: Coatesville