

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

1. **Contracting Activity:** Department of Veterans Affairs, VISN 16, Oklahoma City VAMC. A Justification for Other Than Full and Open Competition request. Purchase request number 635-15-1-071-0008.
2. **Nature and/or Description of the Action Being Processed:** The Oklahoma City VAMC is in an emergent need for a replacement 30 Watt Holmium Laser. The current unit at the OKCVAMC is broken and beyond economical repair for a near end of life unit. This laser is currently used in stone cases which are done a frequent basis at the OKCVAMC. The purchase of an emergent replacement of our Holmium laser – for an Olympus Dornier HLS30W Holmium YAG 30 Watt Laser System from Olympus would be awarded under a new firm fixed price contract.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The OKCVAMC has a patient base that requires stone cases. This specific type of laser has been determined by the Surgery Service based on medical expertise, professional knowledge, and experience using this specific laser. The Olympus Dornier HLS30W Holmium YAG 30W Laser provides accurate, effective laser energy for eliminating stones with maximum control and minimal tissue damage. The HLS30 is effective on all types of stones, regardless of composition, utilizing up to 30 watts of powerful laser energy where needed. It also have the flexibility to treat soft tissue for ablation, incision, or coagulation. A three pedal wireless foot switch allows the surgeon to be in control of the laser. The Holmium YAG 30W Laser is valued at \$81,500.00 with a selling price of \$48,000.00. The price of the system is set by Olympus America, Inc. with the company's catalog pricing that is set on the open market for all medical facilities, either private, public, or Federal. The need for this laser has been established in December 2014 and has requested delivery as soon as possible. The medical center has identified that patients would benefit from the replacement of the Holmium Laser. Because of the current unit being inoperable, surgery stone cases are being denied for fee basis and a replacement unit is needed as soon as possible to continue to provide care for our Veterans. These stone cases are currently on hold and are not being approved due to the need of a working laser. Stone cases are cases where the stones are broken up in the ureteral tract or the kidneys using the holmium laser in a surgical procedure by inserting a laser fiber into a scope through the urethra and activating the laser to break up the stone into small enough pieces in order to pass.
4. **Statutory Authority Permitting Other than Full and Open Competition:**
  - ( ) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
  - (X) (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):** Urgent and compelling need under FAR 6.302-1 unacceptable delays in fulfilling this requirement would occur. These cases are not being approved for fee basis and are being delayed. A replacement unit for the VA in Oklahoma City as soon as possible as to not delay patient care. An "or equal", substitute, or alternate holmium laser will not meet agency requirements due to the complex, specialized, and unique surgical

procedures this laser is being used for in surgical stone cases. A Holmium YAG 30 W Laser is required to ensure compatibility, consistency, continuity, and stability with the instruments that are currently being used for surgical procedures. The OKCVAMC already used an Olympus Dornier Holmium YAG 30W Laser to perform stone cases surgical procedures. This procurement is to purchase a replacement of the broken laser already being used in surgery. As surgical staff already uses the Holmium Laser the introduction of alternative or alternate equipment may require more staff training and could jeopardize patient safety due to staff unfamiliarity with another laser. It is imperative that an Olympus Dornier Holmium YAG 30W Laser be purchased. There is no other vendor who supplies the specific Olympus Dornier Holmium YAG 30W Laser that is mandatory for this procurement. As there are no authorized vendors beside the manufacturer of this laser, there is only one reliable and responsible source to procure this laser.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Market research was conducted by both the customer and contract specialist in an effort to find veteran owned and small business entities that could support this request. Market research efforts included but were not limited to a review of historical acquisition information, use of personal knowledge/experience, contract with the requestor and other parties, review of GSA and VET Biz, review of numerous internet sources and catalogs. It was found that Olympus is the only supplier of the Dornier Holmium YAG 30W Laser.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The price of the laser is set by the manufacturer and are the company's open market price as set by the catalog price that is available for all medical facilities either private, public, or Federal facilities. The cost of not competing the laser is not a factor as the open market economies has set the price. The price of this laser is catalog manufacturer pricing, and is comparative to other types of holmium lasers. The price of the Olympus Dornier HLS30W Holmium YAG Laser is deemed fair and reasonable.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** This is an urgent and compelling need and the end user contacted the service and sales rep for the current unit for a replacement laser for the OKCVAMC. A review of internet resources, personal knowledge and experience of the surgical supplies required and the needed performance of the laser and physician historical experiences with products. The contract specialist performed market research through internet sources review, discussions with the end user and Olympus and verified that there is no other laser for this type of surgery procedure without deviations.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** The medical center is in need of increasing their capability to perform stone cases due to an increase of patient volume and needs and to continue with providing care to Veterans who are unable to proceed currently with surgery due without a replacement laser. The physician/surgical staff at the medical center have deemed that the Olympus Dornier HLS30W Holmium YAG Laser is the reason for the improved patient care from this surgical procedure.
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:** The OKCVAMC medical clinician staff continues to conduct market research and review trade professional journals for the new equipment, and surgical instrumentations that would improve the quality of patient care. The continuation of knowledge of the market place for surgical equipment, supplies, and surgical instruments will improve the basis for future competition for procurement of surgical supplies for this type of holmium laser.

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.



Erin Broderick  
Chief Clinical Engineer  
OKCVAMC

12/15/14

December 15, 2014

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.

DENA A. YOUNG 142748

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Date

Title

Facility

- b. **P&C:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Calvin Q. Ma 630986

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