

**DEPARTMENT OF VETERANS AFFAIRS**

**Justification and Approval**

**For**

**Other Than Full and Open Competition**

**1. Contracting Activity:**

Veteran Health Administration (VHA)  
Service Area Office (SAO) – East  
323 North Shore Drive, Suite 500  
Pittsburgh, PA 15212

**Requiring Activity:**

VA North Texas Healthcare System (VANTHCS)  
Dallas VA Medical Center  
4500 S Lancaster Road  
Dallas, TX 75216

**2. Nature and/or Description of the Action Being Processed:**

2237 Number: 549-14-4-100-0416

This is a request for Other Than Full and Open Competition for a Firm Fixed Price Contract for an essential piece of equipment for the VAMC research department in accordance with FAR 6.302-1.

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

Cellvizio Dual Band, manufactured by Mauna Kea Technologies, is a microscopic imaging system designed to provide live, *in vivo* detailed images of internal or external tissues. It shall be used for direct examination of the entire GI tract (including the biliary system) and the Lung. It makes it possible to proceed to "optical biopsies," giving real-time characterization of tissues.

Excitation is conducted by the fibers down to the tissue to be examined where it is focused by some distal optics which defines the field of view (FOV), the lateral and the axial resolution of the system. Endogenous or exogenous fluorescence is then produced, which is collected by the very same individual fiber and redirected towards a single detector, most of the time an avalanche photodiode (APD).

and a galvanometric mirror, providing an overall frame of 9 to 18 frames per second (fps) and even 200 fps by reducing the field of view. Image processing is needed, first to compensate for fiber-to-fiber differences in transmission and background, but also to remove the well-known fiber honeycomb pattern and reconstruct a smooth and readable image.

The following items will be purchased for this system:

1. Item Number CDB-0001; Cellvizio Dual Band system with Confocal processor (1).
2. Item Number LP-0001; ProFlex S300/B microprobe (2).
3. Item Number LP-0004; ProFlex S650/B microprobe (1).
4. Item Number LP-0005; ProFlex S1500 microprobe (1).
5. Item Number LP-0016; NeuroPak J (1). Includes Jacketed CerboFlex Microprobe with metallic sheath, 1 box of 6 implants with caps, 1 stereo holder, 1 set of 50 screws, and 1 screwdriver.
6. Item Number LQ-0005; 3 pack of Quantikit S/Z/miniO-488 (1).
7. Item Number LQ-0006; 3 pack of Quantikit S/Z/miniO-660 (1).
8. Item Number LA-0003; NeuroPak implants kit (1).

The total estimated cost of this system is \$251,182.00

**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;
- (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 Cellvizio Dual Band System has several unique characteristics and benefits. Among them include real-time in situ microscopy, of particular interest can be:

- Accessing anywhere in the animal with the minimally invasive microprobes
- Acquiring movies by simply placing the microprobe in contact with a fluorescent tissue
- Taking advantage of in vivo sub-cellular resolution to complement current imaging capabilities (MRI, PET/CT, SPECT, Ultrasound, whole-body optical systems...)
- Dynamically following cellular and molecular interactions in situ
- Studying biodistribution and tissue targeting

- Coupling morphological with functional imaging
- Monitoring physiological and functional changes with anatomical context
- Evaluating the complexity of pathological or infectious pathways

A common technical specification is often the simultaneous illumination and detection in multiple channels, led by a critical need for unambiguous image co-registration at different wavelengths, even at microscopic scale, and despite relatively rapid tissue motion. Such simultaneity is of course strongly demanded, for instance, when observations involve processes, which are expected to last a very short time, like Förster Resonant Energy Transfer (FRET). The only source capable of providing this type of system is Mauna Kea Technologies.

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

This is a proprietary system manufactured by Mauna Kea Technologies. No other source can manufacture this system. An intent to sole source was posted to FBO on 07/21/14 and closed on 07/25/14. No responses were received, further confirming that Mauna Kea Technologies is the only source capable of satisfying this requirement.

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

The IGCE for this system is \$251,182.00.

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

An intent to sole source was posted to FBO on 07/21/14 and closed on 07/25/14. No responses were received, further confirming that Mauna Kea Technologies is the only source capable of satisfying this requirement.

**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. An intent to sole source was posted to FBO on 07/21/14 and closed on 07/25/14. No responses were received, further confirming that Mauna Kea Technologies is the only source capable of satisfying this requirement.

**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:**

This is a proprietary system manufactured by Mauna Kea Technologies, Inc. No other source can manufacturer or distribute this system. The Research Office will continue to survey the market for other sources that can provide similar equipment for future acquisitions.

**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.

**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.

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