

Service Area Office, East  
Department of Veterans Affairs  
323 North Shore Drive, Suite 500  
Pittsburgh, PA 15212

Memorandum 2011-003  
December 28, 2010

Attachment A: Request for Sole Source Memo Format

**DEPARTMENT OF VETERANS AFFAIRS**

**Justification and Approval**

**For**

**Other Than Full and Open Competition**

1. **Contracting Activity:** *Department of Veterans Affairs, VISN 04, Louis A. Johnson VA Medical Center*  
Justification for Other Than Full and Open Competition.  
Equipment purchase of the Ekos Sonic Mach 4E Endovascular System

2. **Nature and/or Description of the Action Being Processed:**  
An equipment purchase of the Ekos Sonic Mach 4E Endovascular System

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

EKOS is the only device that uses ultrasound energy with tPA for thrombolysis. This is advantageous because limiting the lytic agent used during thrombolysis is safer for the patient. Ultrasound energy drives the tPA into the thrombus and a sensor alerts the user when thrombus has resolved. Fewer contrast studies are needed to monitor thrombus resolution.

Other methods of providing lytic agents are available, but all of them use more tPA. There is pulse spray thrombolysis whereby a device pulses tPA into a vessel with thrombus at a certain volume and rate. More tPA is delivered because the pulse sprayer does not deliver tPA into the thrombus as effectively as ultrasound energy. The patient periodically needs a follow-up contrast study to assess thrombus resolution.

Another method uses a catheter that either has a hole on its end or many holes on the side where tPA can be dripped through. This is the least effective way to deliver tPA because tPA is not pushed into a thrombus. This method takes the longest for thrombus to resolve and more tPA is used unless thrombus burden is reduced initially.

Overall, the EKOS system is superior in addressing thrombolysis because it reduces the amount of lytic agent by using ultrasound energy. No other equipment offers this method.

4. **Statutory Authority Permitting Other than Full and Open Competition:** *41 USC §253(g), as implemented by FAR 6.302. The specific paragraph must be cited. Most likely, only the -1 or -2 authorities will be cited. Please be aware that failure to adequately plan for future requirements does not constitute appropriate use of the unusual and compelling urgency statutory authority.*

( X ) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy

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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):**

**Only One Responsible Source (FAR 6.302-1)** – To my knowledge, the Ekos Sonic Mach 4E Endovascular System is the only device that uses ultrasound energy with tPA for thrombolysis

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Ekos is the only known vendor, at this moment, capable of providing this system with the least amount of risk regarding unacceptable delays in fulfilling this facility's requirements.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The price of this system is cannot be compared to similar systems because it is the only device available.

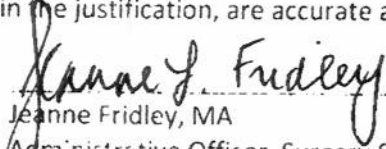
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research revealed that this particular system is not available through any FSS contract and are available only in the open market.

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.

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:** None.

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.

  
Jeanne Fridley, MA  
Administrative Officer, Surgery Service  
Louis A. Johnson VA Medical Center


3/16/12  
Date

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13. Approvals in accordance with FAR 6.304 *... part of the justification*

- 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 Timothy L. Russell  
Title Contracting Officer  
Facility 540

3-20-12  
Date

- b. One Level Above the Contracting Officer:

  
Brent M. Burns  
Supervisory Contract Specialist  
LAJ VAMC

03/20/2012