

## DEPARTMENT OF VETERANS AFFAIRS

### Justification and Approval (J&A) For Other Than Full and Open Competition (>SAT)

**Acquisition Plan Action ID:** 36C242-19-AP-3283

**1. Contracting Activity:**

Department of Veterans Affairs, VISN 02, James J. Peters VA Medical Center 130 West Kingsbridge Road, Bronx New York 10468. **Organizational Activity;** James J. Peters VA Medical Center seeks to purchase brand name Angiodynamics Nanoknife system through 2237#526- 19-4-3086-0536 on a non-competitive acquisition.

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

This request is to procure as a sole source, firm-fixed price award Angiodynamics Nanoknife ablation system for Bronx VAMC. The introduction of the new system will help doctors provide better patient care for Cancer treatment. There is no other comparable nanoknife system. It is proprietary to Angiodynamics.

The nanoknife system is used to deliver a series of high voltage direct current electrical pulses between two electrodes within a targeted tissue area. The following are mandatory minimum technical specification requirements:

- ITEM#20300101-US-Angiodynamics nanoknife system
- ITEM#7200-Accusync 5-Lead System
- ITEM#H787204001070-15 cm IRE Single Electrode, packaged US only
- ITEM#H787204001080-25 cm IRE Single Electrode, packaged US only
- Operational and Service Manuals

The estimated Value of this procurement:

The period of performance for delivery, installation and training will be within 120 days of award.

**FAR13.5 Simplified Procedures for Certain Commercial Items:** This procurement is for Angiodynamics Nanoknife in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and is restricting competition to Brand name only (Angiodynamics) as allowable under FAR 11.105-Items peculiar to One Manufacturer.

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

The JJP VAMC needs an Angiodynamics Nanoknife ablation system. The Angiodynamics Nanoknife procedure is an ablation procedure that involves the delivery of a series of high-voltage direct current electrical pulses between two electrodes placed within a targeted area of tissue. The electrical pulses produce an electric field which induces electroporation on cells within the target area. Electroporation is a technique in which an electrical field is applied to cells to increase the permeability of the cell membranes through the formation of nanoscale defects in the lipid bilayer.

After delivering enough high voltage pulses, the cells surrounding the electrode will be irreversibly damaged. This mechanism which causes permanent cell damage is referred to as Irreversible Electroporation (IRE). The nanoknife ablation system is similar in that it destroys soft tissue in the body, but it achieves ablation through alternative modalities. The nanoknife, with six outputs is indicated for the surgical ablation of soft tissue. Used under general anesthesia, patients experience a non-invasive insertion through the skin directly into and around cancer tumors and sometimes open or keyhole surgery is used. Short pulses of electricity fire between the needles for several minutes. The electrodes may be repositioned, and the process repeats until the whole tumor and a small area around tissue is treated. These pulses of electricity destroy the tumor, leaving the surrounding tissue, veins, nerves and ducts unaffected. Healthy cells can then grow back and regenerate within the area. Nanoknife is different from other treatments like cyberknife and traditional surgery in that it can be done quickly and painlessly, and success evaluated much more quickly. This is what will meet the agency's need.

4. **Statutory Authority Permitting Other than Full and Open Competition:** 41 USC §3304 (a)(1), as implemented by FAR 6.302-1: Only Angiodynamics Nanoknife will satisfy the agency's need at this time.

- (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):**

As stated in section III above, nanoknife ablation is the removal or destruction of body tissue. Other forms of ablation include microwave, radiofrequency and cryoablation. The nanoknife system is used in open, laparoscopic and percutaneous procedures. Electroporation is a phenomenon that occurs in cell membranes as cells are exposed to an electrical field of sufficiently high intensity. The electric field acts as a physical stimulus, bringing about alterations in cell membranes that result in increased permeability. Nanoknife is a new technology used in surgical procedures. There is no other technology available to treat pancreatic cancer percutaneously or with open surgery. Live cells near bio ducts or vascular structures have a higher complication rate when using thermal ablation, (IRE) prevents injury of adjacent structures through radiation therapy for cancer treatment.

Accordingly, Angiodynamics, Inc. is the only firm capable of providing the supplies and services described in Section II and III above without the Veteran's Health Administration experiencing unacceptable delays in fulfilling its requirements.

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

An "Intent to sole source notice" was posted to FBO seeking sources for the equipment. The result was that there was one (1) positive response from FBO, an vendor. A quick search through GSA E-buy showed zero (0) vendors with the equipment on contract. A quick NAICS search "339112" keyword "Nanoknife system" through Veterans Information Pages (VIP) showed the potential for 65 SDVOSB or VOSB vendors that could supply the equipment. A quick search NAICS "339112" and Keyword "Nanoknife system" through Small Business dynamics (DSBS) search engines showed that there are zero (0) potential vendors available to supply equipment. CS consulted a representative of Angiodynamics, the Original Equipment Manufacturer (OEM) and received written confirmation that Angiodynamics, Inc. is the sole proprietary owner, supplier and manufacturer of the Nanoknife system and is the only entity authorized to provide installation and training. They have one equipment distributor, , who only places orders with Angiodynamics but delivery of the equipment comes directly from Angiodynamics, not .

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

Contracting Specialist performed reviews of previous purchases on FPDS and independent review sites specifically regarding costs of the product with required nanoknife items. CS has determined that the price is fair and reasonable to the federal Government. CS will also seek any discounts as part of purchase of the requirement.

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

As described in section VI above, market research was conducted, to include consulting with a Northeast manager at Angiodynamics, Inc. The market research consisted of posting intent to sole source notices and checking all mandatory search engines available to see if the equipment was available for purchase by means of "rule of two" or other means.

The result was conclusive, provided a letter (on their letterhead) stating that even though they have one authorized equipment distributor who can place orders , there are zero potential vendors capable of actually supplying the equipment, capable of performing the installation, implementation and training needed to make the project a success. the manufacturer is the only entity able to fulfill all the requirements of this procurement.

Additionally, this requirement is subject to the non-manufacturer rule, and there are no waivers in place to allow an SDVOSB or VOSB vendors to be able to supply the equipment alone. And as already stated, cannot provide installation or training.

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

Angiodynamics product requirements have been custom-tailored to match with their own proprietary specifications.

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

Angiodynamics, Inc.

**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:**

In order to remove or overcome barriers to competition in future acquisition for this requirement, the agency would have to replace the entire physiological system. The time and cost to replace all equipment and the down time associated with training technicians would not be cost effective. Therefore, no other source can provide proprietary components required to meet the Government's need. Additionally, the NanoKnife is currently a unique technology proprietary to Angiodynamics. It currently has no competitors.

**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.

  
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Date

**13. Approvals in accordance with the [VHAPM Part 806.3 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.

  
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Date

Network Contracting Office, NC02

- b. **One Level Above the Contracting Officer (Required over SAT but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

  
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Date

Network Contracting Office, NC02