

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID:36C249-19-AP-0055

1. **Contracting Activity:** Department of Veterans Affairs, VHA, NCO 9, 1639 Medical Center Parkway Suite 400, Murfreesboro, TN 37129
PR# 626-19-1-200-0014
2. **Nature and/or Description of the Action Being Processed:**
The Nashville VA Medical Center requires Therakos Cellex Photopheresis Procedural kits and lights for their Therakos Cellex Photopheresis System for the period of 11/1/2018-10/31/2019. The estimated value is \$485,470.00.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:**
The Nashville VA Medical Center requires Therakos Cellex Photopheresis procedural kits and light assemblies for blood treatment in patients suffering from cancer.
4. **Statutory Authority Permitting Other than Full and Open Competition:** Sources Sought notice was published to FBO on 10/5/2018 under 36C24919Q0018. Zero vendors responded to the sources sought notice as a potential supplier of the requirement. This award was made to Therakos in the prior fiscal year under award VA249-18-P-0342 in the amount of \$942,580. Additionally, a search was conducted in VIP under NAICS 339113 key word "photopheresis". Zero vendors were returned.

(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):**
Therakosis the Original Equipment Manufacturer (OEM) of the Cellex Photopheresis System. As the OEM, Therakos is the only vendor that can provide the replacement parts to ensure that the equipment continues to operate.

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

A Sources Sought Notice was posted to FBO on October 05, 2018 and closed on October 11, 2018. The notice detailed the requirement for 75 cases of Therakos Cellex Photopheresis procedural kits with product code CLXUSA and 4 cases of Light Assembly with product code CLXLGT for the Nashville VAMC. Following the closing, zero responses were received.

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

Based on market research and previous acquisition 626-18-1-200-0014, the Contracting Officer has determined that prices are fair and reasonable. Additionally, no other vendors responded to FBO posted sources sought notice.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted: Market research was conducted, but due to the sole source nature of this procurement no other vendors were found. Source sought notice was posted to FBO and returned 0 results.

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

Therakos provided a sole source letter explaining that the Cellex Photopheresis system and products connected to its operation and maintenance are proprietary to Therakos and there are no authorized vendors or distributors except then OEM.

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

Sources sought notice posted to FBO for the period of October 5, 2018 to October 11, 2018 returned zero interested vendors.

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 Department of Veterans Affairs will continue to seek vendors capable of providing these supplies in future procurements. At the present time, based on available market research, there are no other vendors available to provide the required items.

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.

VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP
Attachment 2: Request for Sole Source Justification Format >SAT

Allison Hanlon
Chief of Dermatology
TN Valley Healthcare System

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.

Mark Bentley
Contracting Officer
NCO 9 Supply East

- 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.

Jon E. Doliana Sr.
Branch Chief
NCO 9 Supply East