

DEPARTMENT OF VETERANS AFFAIRS

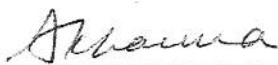
Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, Great Lakes Acquisition Center, NCO 12, 115 S. 84th Street, Milwaukee, WI 53214 on behalf of Hines VA Hospital, 5000 South 5th Avenue, Hines, IL 60141. This is a justification for other than full and open competition. The purchase request number is 578-12-3-969-0276.
2. **Nature and/or Description of the Action Being Processed:** Justification and approval for other than full and open competition for a one-time buy of Trabectome surgical instrument for the minimally invasive treatment of glaucoma, on a sole source basis to NeoMedix Corporation.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The Trabectome (registered trademark by NeoMedix Corporation) system consists of a console on a roller stand with specially prepared one-time-use procedure packs and a left and right Goniolens. The Trabectome system is manufactured and distributed by NeoMedix Corporation. The estimated cost of the system is \$40,000.00.
4. **Statutory Authority Permitting Other than Full and Open Competition:** This instrument is being procured under the authority of FAR 6.302-1, 41 U.S.C. 253(c) (1). Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements.
5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** Trabectome is a minimally evasive surgical procedure for the treatment of glaucoma. The unique characteristic that differentiates Trabectome from other glaucoma technologies is that it is the only FDA allowed surgical product for glaucoma that opens trabecular meshwork using an ab-interno surgical approach. The Trabectome system has secured 4 U.S. Patents (6979328, 7785321, 7842034 and 07959641) as well as FDA approval 510(K) # K061258. NeoMedix's intellectual property position makes it unlikely that competitive products will be offered through other sources. It would not be practical or cost effective to purchase other than the recommended Trabectome system in order to meet VA mission requirements.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Market research indicates the Trabectome system is distributed exclusively by NeoMedix Corporation. The manufacture does not maintain a third party distribution system in the United States but does abroad.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** NeoMedix Corporation lists the system publically at \$39,775.00 and have sold to other VA's at that price (Pennsylvania: VA244-12-P-2308, Gainesville, FL: VA248-12-P-3134 and Bronx, NY: VA243-12-P-1272) in FY12.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** An internet search of glaucoma surgeries revealed Micropulse Laser Trabeculoplasty (MLT), Selective Laser Trabeculoplasty (SLT) and Canaloplasty as alternative methods for treatment. Trabectome is the only FDA allowed surgical product for glaucoma that opens trabecular meshwork using an ab-interno surgical approach, therefore the other methods were not considered.
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:** No other vendors exist for the Trabectome surgery equipment.
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 VA Ophthalmology department will continue to monitor technology to provide the best and state-of-the-art glaucoma treatments available.
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.

Signed For
by
ANURADHA KHANNA, M.D.



Jay Perlman, M.D.
Ophthalmology, Surgery
Hines VA Hospital

8/16/12

Date

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.

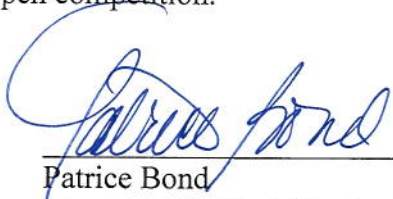


Steve Maier
Contracting Officer
NCO 12

8/15/12

Date

- b. **Team Manager:** I certify the justification meets requirements for other than full and open competition.

A handwritten signature in blue ink, appearing to read "Patrice Bond", is written over a horizontal line.

Patrice Bond
Manager, Medical Sharing Team
NCO 12

8/15/2012

Date