

LIMITED SOURCES JUSTIFICATION

ORDER >\$150,000

FAR PART 8.405-6

Acquisition Plan Action ID: VA260-16-AP-4880

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in par. 3 below is sole source, therefore, consideration of the number of contractors required by FAR Subpart 8.4 – Federal Supply Schedules, is precluded for the reasons indicated below.

Restricted to the following source: Provide *original manufacturer's* name for material or contractor's name for service. (If a sole source manufacturer distributes via dealers, *ALSO* provide dealer information.)

Manufacturer/Contractor: Medivators (distributor is Surgical Tools Inc).

Manufacturer/Contractor POC & phone number: Dave Handa 800-444-4729

Mfgr/Contractor Address: _____

Dealer/Rep address/phone number: Surgical Tools Inc. / Willie H. Morris / 1106 Monroe St., Bedford, VA 24523 800-774-2040

The requested material or service represents the minimum requirements of the Government.

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs

Seattle VAMC

POC: Michael McDonald

VISN:

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(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:

This requirement is for FDA approved automated endoscopic reproprocessors. The only FSS contractor who has FDA validation for all of the required endoscopes is Medivators. They sell through Surgical Tools on the FSS.

(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:

The required AER's must be approved/cleared by the FDA and have the ability to high level disinfect all endoscopes to include open and closed elevator channel duodendoscopes. The only FDA approved company for this is Medivators. See documentation in eCMS briefcase "P02 FDA Mediators only approved"

(b) ESTIMATED DOLLAR VALUE: \$286,642.61

(c) REQUIRED DELIVERY DATE: Prefer first week in August.

(4) IDENTIFICATION OF THE JUSTIFICATION RATIONALE (SEE FAR 8.405-6), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE. (CHECK ALL THAT APPLY AND COMPLETE)

Specific characteristics of the material or service that limit the availability to a sole source (unique features, function of the item, etc.). Describe in detail why only this suggested source can furnish the requirements to the exclusion of other sources.
The FDA approves automated endoscope reprocessors and Medivators is the only FSS contract holder approved.

A patent, copyright or proprietary data limits competition. The proprietary data is:
(If FAR 8.405-6(a)(2)iii before posting. Do not include specific proprietary data. Only mention the type of equipment, procedure, etc. to show that proprietary supplies or services are being procured.)

These are "direct replacements" parts/components for existing equipment.

The material/service must be compatible in all aspects (form, fit and function) with existing systems presently installed/performing. Describe the equipment/function you have now and how the new item/service must coordinate, connect, or interface with the existing system.

The new work is a logical follow-on to an original Federal Supply Schedule order provided that the original order was placed in accordance with the applicable Federal Supply Schedule ordering procedures. The original order must not have been previously issued under sole source or limited source procedures.

An urgent and compelling need exists, and following the ordering procedures would result in unacceptable delays.

(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.4 TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:

As Medivators are the only approved FDA company for the automated endoscope reprocessors and they are providing pricing off their distributors FSS contract (Surgical Tools), this is the best value to the government to proceed with a delivery order off Surgical Tool's FSS contract.

(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED:

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
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The FDA requires automated endoscope reprocessors to be approved. The only approved is Medivators who sells through Surgical Tools on their FSS contract.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

See the eCMS briefcase file for FDA's approval of Medivators for the open/closed duoendoscope validation as to why only Medivators will work.

(8) A STATEMENT OF THE ACTIONS, IF ANY, THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS THAT LED TO THE RESTRICTED CONSIDERATION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES OR SERVICES IS MADE:

None—it is up to the suppliers to get FDA approval.

(9) 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. I understand that processing of this limited sources justification restricts consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4. *(This signature is the requestor's supervisor, fund control point official, chief of service or someone with responsibility and accountability.)*

_____ SIGNATURE	_____ DATE
Michael McDonald NAME	Chief, Biomedical Engineer TITLE
VA Puget Sound Healthcare System FACILITY	FMS/Biomedical Engineering SERVICE LINE/SECTION

(10) APPROVALS IN ACCORDANCE WITH THE [VHAPM, Volume 6, Chapter VI: OFOC SOP](#):

a. CONTRACTING OFFICER'S CERTIFICATION (required): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

_____ CONTRACTING OFFICER/DESIGNEE'S SIGNATURE	_____ DATE
Karen Rhodes, Contracting Officer NAME AND TITLE	NCO20 FACILITY

b. Director of Contracting/DESIGNEE: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

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SIGNATURE

DATE

NAME

NCO20 Director of Contracting