

MEMORANDUM TO THE FILE

Subj: JUSTIFICATION FOR USE OF OTHER THAN FULL AND OPEN COMPETITION
FOR AN ACQUISITION UNDER THE SIMPLIFIED ACQUISITION THRESHOLD

1. Organization/Line Office:

Network contracting office VISN 22/VA Long Beach Healthcare System (VALBHS)

2. Description of Action being approved:

This solicitation is requesting a firm fixed price purchase for KARL STORZ D-Light C Photodynamic Diagnostic (PDD) system Blue Light Cystoscopy with Cysview for the VALBHS via the open market.

3. Description of Product, Supplies or Services:

The KARL STORZ PDD system enhances detection and treatment of NMIBC (Non-muscle invasive bladder cancer). The PDD system uses a photosensitive marker, Cysview (a registered trademark of Photocure, ASA), which is introduced into the bladder, absorbed and converted into a pigment that is deposited into cancerous tissue. At the heart of this system is the KARL STORZ D-LIGHT C light source as well as specially adapted telescopes. Under blue light excitation, this pigment emits red fluorescence while normal tissue appears dark blue.

The items being requested are as follows:

Note: Please review solicitation attached to this justification for additional product information, components, and details.

The Cystoscopic System:

- Must be compatible with Karl Storz D-Light PDD telescopes
- The light source must enable white light cystoscopy and blue light (wavelength 360 – 450 nm) fluorescence cystoscopy.
- PDD endoscopes must be compatible with use of optical imaging agent Cysview for Intravesical Solution to view tissue specific fluorescence images.
- Must have operating time to 400 hours

4. An identification of the statutory authority permitting other than full and open competition. (Requesting Office completes with assistance of Contract Specialist)

- a. FAR 13.1 06-1(b)(1)(i) states for purchases not exceeding the simplified acquisition threshold, Contracting Officers may solicit from one source if the Contracting Officer determines that the circumstances of the contract action deem only one source reasonably available (e.g., urgency, exclusive licensing agreements, brand-name or industrial mobilization).

- b. As required by FAR 13.106-3(b)(i), this memorandum explains the limited sources for this acquisition, as only one source will be solicited for this requirement (or for a portion of the requirement) and the requirement (or portion of the requirement to be sole-sourced) is not expected to exceed the simplified acquisition threshold.

5. Determination for use of other than full and open competition:

(Select all that apply)

A. ☐ ONLY ONE RESPONSIBLE SOURCE (select all that apply):

1. ☐ RESTRICTIVE RIGHTS. The source has established proprietary rights, limited rights in data, patent rights, copyrights or secret processes in the item or service required.
2. ☒ EXCLUSIVE LICENSING AGREEMENTS. The item or service is only available from the Original Equipment Manufacturer (OEM), or there is only one authorized distributor or technical representative for the OEM.
3. OTHER REASONS.

B. ☒ BRAND NAME

This acquisition is restricted to the following Source: Manufacturer: KARL STORZ Endoscopy-America, Inc. 2151 E. Grand Avenue El Segundo CA 90245
www.karlstorz.com

Manufacturer POC and Phone Number: Matt Hooper 800-421-0837 Ext: 7577

C. ☐ URGENT AND COMPELLING

The supplies or services are of such unusual and compelling urgency that the Government would be seriously injured unless the agency is permitted to limit the number of sources from which it solicits quotes. Urgent requirements are supplies or services that will result in a work stoppage, or are mission critical and the routine processing time would result in injury to the Government. The determination that the procurement for the above item/service is an urgent and compelling requirement is based on the following:

This equipment will help physicians to clearly identify tumorous tissue. It is the only FDA-approved technology that is clinically proven to detect more Ta/T1 bladder cancer lesions vs. white-light cystoscopy alone, and promote a more comprehensive tumor resection. BLCC is recommended to decrease recurrence of bladder cancer and avoid complications associated with TURBT.

Currently, the VALBHS carries Karl Storz D-Light PDD telescopes and optical imaging equipment. In an effort to provide the Veterans with the highest level of care, compatibility is a crucial element for the success of the VALBHS.

6. Certifications

As the technical or requirement personnel, I certify that the evidence of the supporting data that forms the basis of this justification is complete and accurate.

_____ Technical/Requirements Personnel	_____ Martha Kendricks	_____ Date
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_____ Fredy A. Arteaga Contracting Officer	_____ Date
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