JUSTIFICATION FOR AN EXCEPTION TO FAIR OPPORTUNITY (JEFO) KARL STORZ ENDOSCOPY VIDEO SYSTEM

- (1) Defense Logistics Agency (DLA) Troop Support, Medical Supply Chain, Capital Equipment Division, is the contracting activity.
- (2) The action submitted for approval is a JEFO for an acquisition from Karl Storz Endoscopy-America under Patient Monitoring and Capital Equipment (PMCE/ ECAT) Contract SPE2D1-20-D-7007 which has an expiration date of September 09/15/2025. The required items are Karl Storz's Flexible Video Cystoscopes and accessories for the Surgery Service at Minneapolis VA (MVAHCS).
- (3) This acquisition is for the purchase of the following items for MVAHCS:

Requisition Number:

Supplier: Karl Storz Endoscopy- America

Original Equipment Manufacturer (OEM): Karl Storz Endoscopy - America

Required items:

 Flexible Video Cystoscope, HD-View Manufacturer part number: 11272VHK

Quantity: 30 each

Unit Price: Subtotal:

• Container system, Flex CMOS Videoscopes Manufacturer part number: KSZ-39406AS

Quantity: 30 each Unit Price: Subtotal:

Total Estimated Dollar Value:

(4) The authority waiving the competition requirements is FAR 16.505(b)(2)(i)(B): only one awardee is capable of providing the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized.

MVAHCS is seeking replacement thirty (30) Karl Storz's Flexible Video Cystoscopes (Urology) for the Surgery Service. The current cystoscopes are no longer supported by the manufacturer, and service and consumable products have limited availability.

The existing Karl Storz's Flexible Video Cystoscopes to be replaced are accessories/ components of the Karl Storz's Video Endoscopy Systems used during surgical procedures. Karl Storz is the original equipment manufacturer (OEM) of the video endoscopy systems and the requested flexible video cystoscopes. The Karl Storz's Flexible Video Cystoscopes are proprietary scopes and cannot be used with another brand of video endoscopy System. Purchasing any other noncompatible scopes would require replacement of the entire Video Endoscopy System at the site. Karl Storz's video endoscopy system (aka – "video tower") is comprised of light source, video

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processor, image recorder, insufflator, cart, etc. and compatible with Karl Storz's endoscopes (cystoscope) only.

MVAHCS owns many other Karl Storz's video endoscope products that are also exclusively compatible with the same Karl Storz's video endoscopy system.

The use of this authority is necessary since the Urology Department at MVAHCS requires Karl Storz's Flexible Video Cystoscopes. The devices are needed because there are no flexible video cystoscopes from manufacturers other than Karl Storz that can be compatible with Karl Storz's Image1 S Camera Systems- the existing video endoscopy systems at MVAHCS. Karl Storz is the only source for the replacement flexible video cystoscopes.

The following is the minimum requirements for the flexible video cystoscope for Urology:

- (a) The device shall be compatible with the existing Video Endoscopy Systems (Karl Storz Image1 S Camera Systems) at the site
- (b) The device shall have deflection of distal tip of -140 degrees down to +210 degrees up
- (c) The device shall have 0-degree direction view
- (d) The device shall have working length of 37 cm
- (e) The device shall have working channel of 7 Fr.
- (f) The device shall have sheath size of 16 Fr.

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- (g) The device shall have distal tip outer circumference of 10.9 Fr.
- (h) The device shall have 6 o'clock position of working channel
- (i) The device shall have detachable working channel with various attachments, with or without stopcocks, that are available to the user.
- (j) The device shall have a suction port equipped with a suction valve that allows rapid treatment and emptying of the bladder.

The Karl Storz Flexible Video Cystoscopes supplied by Karl Storz is the only flexible video cystoscope for Urology currently on PMCE/ ECAT that can meet all of the VA's minimum requirements.

(5)	The Karl Storz Flexible Video Cystoscopes are available on Karl Storz's PMCE/ECAT Contract
	SPE2D1-20-D-7007. The contract pricing has previously been determined fair and reasonable
	via comparison with commercial pricing, invoices, and other than certified cost or pricing data.
	Market research was performed in April 2022 by MVAHCS on similar flexible video

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cystoscopes from competitors;		

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	system for vendors/ supplier	omedical Engineer performed additional market research in ECAT so other than Karl Storz that can provide similar flexible video
	cystoscopes.	
(7)	There are no other facts supp	porting the use of this JEFO.
(8)		e VA will continue to perform market research of video endoscopy ptable sources for future acquisitions. However, any new equipment ne VA's requirements.
(9)		I hereby certify that the information contained in this justification is e best of my knowledge and belief.
		GIUNTA.ANTHO Digitally signed by GIUNTA.ANTHONY.1229197211 NY.1229197211 Date: 2022.06.24 13:04:50 -0400'
	Date	ANTHONY GIUNTA
		Contracting Officer, FSD
		uirements that form the basis of this justification are accurate, that rernment's minimum needs and that this justification is accurate and knowledge and belief.
	-	<u> </u>
		1271731307
	Date	Biomedical Engineer, FSDC

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Date	
	Chief, Critical Care IST, FSDC

I have reviewed this justification and recommend approval.