Soterix Medical NIRSIT Standard System
36C250-26-AP-3243

DEPARTMENT OF VETERANS AFFAIRS

Justification for Single Source Awards IAW RFO 12
For
Over Micro-Purchase Threshold but Not Exceeding the Simplified Acquisition Threshold

Acquisition Plan Action ID: 36C250-26-AP-0488

1. **Contracting Activity:** The Department of Veterans Affairs, Veterans Integrated Service Network (VISN) 10, Cleveland Veterans Affairs Medical Center (CLE VAMC) Network Contracting Office (NCO) 10.

   Transaction: 541-26-3-250-0488

2. **Brief Description of Supplies/ Services required and the intended use/Estimated Amount:**

   Network Contracting Office (NCO) 10 intends to award a new firm-fixed-price sole-source purchase order for one (1) Lumenis BE Digital Duet 2.0 ophthalmic laser system, including installation, calibration, and on-site clinical training, for the Louis Stokes Cleveland Veterans Affairs Medical Center (CLE VAMC) Eye Clinic. The equipment will be used to perform Selective Laser Trabeculoplasty (SLT) and Nd:YAG laser procedures, providing advanced ophthalmic laser treatment capabilities necessary to support the safe and effective delivery of patient care.

   1 EA Lumenis BE Digital Duet 2.0 Ophthalmic Laser System
   1 EA Delivery, Installation, Calibration, and On-Site Clinical Training

   ESTIMATED DOLLAR VALUE: [redacted]

   REQUIRED DELIVERY DATE: 30 Days ARO

3. **Unique characteristics that limit availability to only one source, with the reason no other supplies or services can be used:** The Government requires an anterior segment ophthalmic laser platform capable of performing Selective Laser Trabeculoplasty (SLT), Nd:YAG laser capsulotomy, laser peripheral iridotomy, posterior membranectomy, and vitreous opacity illumination using a single integrated system. The requested Lumenis BE Digital Duet 2.0 is an all-in-one digital SLT/YAG laser platform that combines both laser modalities into one system, allowing clinicians to switch between SLT and Nd:YAG treatments at the touch of a button. The system is the first and only digital SLT/YAG platform that incorporates an integrated high-definition digital camera capable of capturing images and videos before,

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during, and after treatment, automatically generating digital treatment reports, and connecting directly to the facility's electronic medical record (EMR) through DICOM, LAN, Wi-Fi, and USB connectivity. The system also provides a 15.6-inch Full HD touchscreen, heads-up display, automated reporting, speech-to-text support, superior Smart-V illumination, a highly accurate Super Gaussian beam profile that achieves photodisruption using lower energy levels, ADA-compliant two-leg table design for wheelchair accessibility, and future upgrade capability to include the Smart532 green photocoagulator with SmartPulse technology. The Digital Duet is manufactured in the United States and is supported by Lumenis' nationwide field service organization.

The requested equipment is required to support the clinical needs of the Louis Stokes Cleveland VA Medical Center Eye Clinic by providing advanced laser treatment capabilities for glaucoma and other anterior segment ophthalmic procedures while improving clinical workflow through integrated imaging, digital documentation, and EMR connectivity. The acquisition includes delivery, installation, calibration, on-site clinical training, shipping, and the manufacturer's warranty necessary to provide a complete, fully operational system.

In addition, Lumenis BE has designated Melling LLC dba MellingMedical as the sole source authorized distributor of all Lumenis BE lasers, energy devices, and accessories for the Federal Government. The authorization further states that all manufacturer warranties, services, and preventive maintenance agreements are transferred and honored by Lumenis BE, making MellingMedical the only authorized source capable of providing the required equipment with full manufacturer support for this Federal acquisition.

4. **Description of market research conducted and results or statement why it was not conducted:** The Contracting Officer, working with Eye Clinic Service, conducted market research to identify commercially available ophthalmic laser systems capable of meeting the Government's minimum requirements for the Louis Stokes Cleveland VA Medical Center (CLE VAMC).

   Before beginning that research, the Government identified the minimum functional requirements for the requested equipment. At a minimum, the required system had to provide an integrated ophthalmic laser platform capable of performing Selective Laser Trabeculoplasty (SLT) and Nd:YAG laser procedures, include high-definition digital imaging, support electronic medical record (EMR) connectivity, and include delivery, installation, calibration, on-site clinical training, and all associated components necessary to provide a complete, fully operational ophthalmic laser system.

   On August 6, 2026, the Contracting Officer reviewed GSA Advantage, National Contracts, ECAT, SAM.gov, Interagency Contract Directories, NAC, SEWP, FPDS, SCMC, OMB, and BIC

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using the keywords "Digital Duet." SBA Small Business Search was also reviewed under NAICS 339112 using the same keywords. The SBA Small Business Search identified certified SDVOSB firms under the applicable NAICS code; however, market research did not identify any certified SDVOSB/VOSB capable of providing the required Lumenis BE Digital Duet 2.0 system or an equivalent system meeting the Government's minimum requirements.

Market research determined that the Lumenis BE Digital Duet 2.0 met the Government's minimum functional requirements for this acquisition. The required equipment provides integrated SLT and Nd:YAG laser capability, digital imaging, EMR connectivity, and the functionality necessary to support the clinical requirements of CLE VAMC Eye Clinic.

The Contracting Officer also confirmed with the manufacturer that the required Lumenis BE Digital Duet 2.0 is an open market item. Market research identified Melling LLC dba Melling Medical, an SBA-certified Service-Disabled Veteran-Owned Small Business (SDVOSB) and the sole authorized distributor of Lumenis BE laser systems for the Federal Government, as the only capable source for the required equipment.

The Nonmanufacturer Rule (NMR) applies to this procurement under NAICS 339112, and the SBA has not provided a waiver. Market research determined that the VA and SBA Rule of Two could not be met, as no certified SDVOSB/VOSB vendors were identified capable of meeting the Government's requirement. Accordingly, this procurement is recommended to proceed as a sole-source acquisition to Melling LLC dba Melling Medical.

Contracting Officer's Certification: *Purchase is approv*
ed in accordance with RFO 12. I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

RACHELLE HAMER
Digitally signed by RACHELLE HAMER
Date: 2026.08.06 12:57:48 -04'00'

Rachelle J. Hamer
Contracting Officer
NCO 10