DEPARTMENT OF VETERAN AFFAIRS
Office of Acquisition and Logistics National Acquisition Center
P.O. Box 76 Hines, IL 60141

JUSTIFICATION FOR AN EXCEPTION TO FAIR OPPORTUNITY
(Implements the provisions and authorities of VA Class Deviation, Modeled Revolutionary FAR Overhaul (RFO) Subpart 16.507-6 "Exceptions to Fair Opportunity")

(1) Identification of the agency and the contracting activity.

This Justification for an Exception to Fair Opportunity is on behalf of the Michael E. DeBakey VA Medical Center, located in Houston, TX, executed by the Veterans Affairs National Acquisition Center located in Hines, Illinois.

(2) Nature and/or description of the action being approved.

The activity proposes the issuance of a sole-source delivery order against VA High Tech Medical Equipment (HTME) ID/IQ Contract No. SPE2D119D0018 awarded to Medtronic USA. The proposed delivery order is to acquire an OCL RF UNIT MOBILE: O-Arm for Turn-in/Replacement.

(3) A description of the supplies or services required to meet the agency's needs, including the estimated value.

The Michael E. DeBakey VA Medical Center requires replacement of the Mobile O-Arm to continue the Operating Room (OR) staff's capabilities to perform spinal surgery/diagnosis and through the use of 3D imaging provided by the Medtronic O-ARM's integration with the Houston VAMC owned Medtronic Stealth navigation systems. This equipment must have the ability to capture 3D images and integrate them with the Medtronic Stealth Spinal Navigation System owned by the Houston VAMC. The ability to capture 3D images is clinically important, as it will allow for improved visualization of the patient anatomy during complex invasive procedures.

Purchase Order No. 580B50057
Estimated Cost: $1,109,629.70

(4) An identification of the "exception of fair opportunity" listed under RFO Subpart 16.507-6(b) and the supporting rationale, including a demonstration that the proposed contractor's unique qualification or the nature of the acquisition requires use of the exception cited. If the contracting officer uses the logical follow-on exception, the rationale shall describe why the relationship between the initial order and the follow-on is logical (e.g. in terms of scope, period of performance, or value.

Only one awardee can provide the Mobile O-Arm with the level of quality required and in a manner that meets the highly specialized integration requirements of the current surgical visualization and navigation system. Other C-ARM technologies are available; however, they do not contain the ability to capture 3D images and integrate them with the Medtronic Stealth Spinal Navigation System owned by the Houston VAMC.

The Medtronic O-arm is the only system with a specialized isocentric rotation in fluoroscopy mode trademarked as Iso-Wag™. The system has the flexibility to bring in or remove the O-arm from the sterile field based upon the stage of the procedure or surgeon preferences and an option to use O-arm

during multiple concurrent cases.

The system also allows for 2D and 3D imaging in one device and to be able to complete required imaging without having to go to Radiology Department for pre-op imaging. Medtronic O-arm features Iso-Wag and Advanced Viewing are proprietary technologies developed and owned by Medtronic. These are registered trademarks of Medtronic Navigation, Inc. These options are available only on the Medtronic O-arm platform. The device has native Medtronic Stealth Station Navigation Integration which will be utilizing our existing S8 inventory. Many of the positioning techniques used for orthopedic and neurosurgery cases are robotic and automated which will enhance the surgical outcome.

(5) A determination by the Contracting Officer that the anticipated cost to the Government will be fair and reasonable.

The contracting officer for the resultant order has determined the prices offered to be fair and reasonable for this justification for an exception to fair opportunity. All items are priced at or below the contract price, which was previously determined fair and reasonable at time of contract award, and there have been no significant changes to the industry or market conditions that would result in changes to the reasonableness of the underlying contract prices.

(6) Any other facts supporting the justification.

Houston VAMC will be able to allow for continued use of existing navigation equipment, OR bed/tables, accessory/instruments. The staff are well-trained on these devices and existing equipment further reducing the expense of training for other equipment. This purchase will allow for the best use of existing investments already made in Surgery Department. A replacement O-arm is needed due to unsupported OS and need for a system upgrade.

(7) A statement of the actions, if any, the agency may take to remove or overcome any barriers that led to the exception to fair opportunity before any subsequent acquisition for the supplies or services is made.

All prospective delivery orders are completed by all contract holders. Once an order is placed for proprietary equipment, it is generally not possible to compete follow-on acquisitions for upgrades because the system to be upgraded is proprietary in nature. Future requirements will be handled on a case-by-case basis and all attempts will be made to provide fair opportunity to all contract holders when appropriate.

(8) The contracting officer's certification that the justification is accurate and complete to the best of the contracting officer's knowledge and belief.

By signing this justification, the Contracting Officer hereby certifies that the justification is accurate and complete to the best of their knowledge.

(9) Evidence that any supporting data is the responsibility of the technical or requirements personnel (e.g., verifying the Government's minimum needs or requirements or other rationale for an exception to fair opportunity) and which form a basis for the justification have been certified as complete and accurate by the technical or requirements personnel.

By signing this justification, the Facility Biomedical Engineer hereby certifies that the justification is accurate and complete to the best of their knowledge.

(10) A written determination by the approving official that one of the circumstances within the above cited FAR Part applies to the order.

In consideration of the information contained herein, a determination has been made that this requirement meets the FAR exception, "Only One Capable Source."

CERTIFICATION AND APPROVAL
(Pursuant to the approval authorities of VA Class Deviation, modeled RFO Subpart 16.507-6, "Exceptions to fair opportunity")

TECHNICAL/REQUIREMENTS CERTIFICATION:

I certify that any supporting data that is my responsibility and which forms a basis for the justification is complete and accurate to the best of my knowledge and belief.

ANDREW CHI Digitally signed by ANDREW CHI
Date: 2025.09.15 12:52:01 -05'00'

Date

TCF Biomedical Engineer
Michael E. DeBakey VAMC

CONTRACTING OFFICER CERTIFICATION:
I certify that the justification is complete and accurate to the best of my knowledge and belief.

SHEILA HENDERSON Digitally signed by SHEILA HENDERSON
Date: 2026.01.28 11:52:25 -06'00'

Date

Sheila Henderson

Contracting Officer
VA National Acquisition Center – Hines
High-Tech Medical Equipment Ordering Division

REGINA BLAIR Digitally signed by REGINA BLAIR
Date: 2026.01.29 09:33:02 -06'00'

1/29/26

Date

Regina G. Blair

Chief HTME Ordering Division
VA National Acquisition Center – Hines
High-Tech Medical Equipment Ordering Division

COMPETITION ADVOCATE APPROVAL:

I certify that the justification is complete and accurate to the best of my knowledge and belief.

JOY SMITH Digitally signed by JOY SMITH
Date: 2026.04.17 15:22:39 -04'00'

Date

Joy M. Smith
Head of Contracting Activity
Strategic Acquisition Center and National Acquisition Center