

JUSTIFICATION AND APPROVAL
FOR OTHER THAN FULL AND OPEN COMPETITION

1. **Contracting Activity:** Department of Veterans Affairs (VA)
Strategic Acquisition Center - Frederick
8490 Progress Dr.
Suite 100
Frederick, MD 21701
2. **Nature and/or Description of the Action Being Processed:** The proposed sole source action is to award a firm fixed price purchase order for the procurement of an ILUMIEN Optical Coherence Tomography (OCT) system for the Cardiac Catheterization laboratory at West Roxbury VA Medical Center from St Jude Medical, Inc., 6300 Bee Cave Rd., Building 2, Suite 100, Austin TX, 78746.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The proposed action is to provide delivery and installation of the ILUMIEN Optical Coherence Tomography (OCT) system for the cardiac catheterization laboratory at West Roxbury. The contractor shall provide the capital equipment, installation, and clean up. This is a new contract with a firm-fixed price [REDACTED].
4. **Statutory Authority Permitting Other than Full and Open Competition:** The proposed purchase order may be negotiated without full and open competition pursuant to 41 U.S.C. 253(c), (1), Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1.
5. **Rationale Supporting Use of Authority Cited Above:** In accordance with FAR 6.302-1, procurement of the ILUMIEN OCT system constitutes highly specialized equipment, and this technology is only available from one vendor (St Jude). The ILUMIEN system is the only system that combines fractional flow reserve (FFR) technologies and optical coherence tomography (OCT) in one platform. The combined system offers physicians advanced physiological and anatomical insight to improve the diagnosis and treatment of coronary artery disease. The Ilumien OCT system has an intravascular imaging technology that allows physicians to visualize and measure important vessel characteristics otherwise not visible or difficult to assess with older intracoronary imaging technologies. The OCT coronary imaging technology helps to optimize treatment with stents, and has about 10 times better image resolution and 20 times faster image capture over the current industry standard of Intravascular Ultrasound (IVUS). This efficient technology provides easy visualization, with high resolution images in less than five seconds.

Additionally, the ILUMIEN system works with the Wi-Box™ wireless device to receive hemodynamic data from the catheterization lab wirelessly. Without this equipment there would be unacceptable delays in fulfilling the requirements of the VA Boston Healthcare System Cardiac Catheterization laboratory. St Jude Medical Corp is the only firm in the USA capable of providing the supplies and services described in Section 3 above. Therefore the use of such description in the acquisition is essential to the Government's requirements.

6. **Efforts to Obtain Competition:** Market research was conducted this effort did not yield any additional sources that can meet the Government's requirements. There is no

competition anticipated for this acquisition. Additionally, the proposed action will be synopsized on the Federal Business Opportunities Page in accordance with FAR 5.201.

7. **Actions to Increase Competition:** This item is a commercial item, sold not only to Government customers but to commercial customers alike. [REDACTED]

[REDACTED]. The Government will continue to conduct market research to ascertain if there are changes in the market place that would enable future actions to be competed. All future requirements will be handled on a case-by-case basis to determine any future acquisition strategy.

8. **Market Research:** Market research was conducted using the World Wide Web, GSA and VetBiz.gov. It was determined that St Jude Medical is the only source available with this technology. A search for information yielded an independent report by Diagnostic and Interventional Cardiology Magazine in which it stated the OCT system by St. Jude Medical is the only one of its kind combining FFR technologies and OCT in one platform available in the United States. Volcano Corp manufactures a similar item however it is not available in the US.

9. **Other Facts:** None.

10. **Technical and 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 and belief.

[REDACTED]

[REDACTED]

[REDACTED]

11. **Fair and Reasonable Cost Determination:** I hereby determine that the anticipated price to the Government for this contract action will be fair and reasonable based on a price comparison of the list price of [REDACTED]
[REDACTED] of the list price.

[REDACTED]

[REDACTED]