

# Notice of Intent to Certify Sole Source

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**To:** Interested Parties

**From:** Stacy Baldwin  
Agency Procurement Officer

**Date:** November 28, 2016

**Re:** Sole Source Certification Number **SS5062** for **Volcano Intravascular Ultrasound Catheters and associated disposables**

**Contact Email Address:** [solesource@umc.edu](mailto:solesource@umc.edu)

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## Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5062** for **Volcano Intravascular Ultrasound Systems and associated disposables**, please be advised that UMMC intends to award the purchase of the **Volcano Coronary Intravascular Ultrasound Catheters, Volcano Peripheral Intravascular Ultrasound Catheters, Fractional Flow Reserve Pressure Guide Wires, and Phoenix Atherectomy Systems** to **Volcano, a division of Philips**, as the sole source provider of the **Volcano Intravascular Ultrasound Catheters and associated disposables**.

UMMC issues this notice in accordance with Mississippi state law, policy, and procedures for sole source procurements.

## Sole Source Criteria

1. Where the compatibility of equipment, accessories, or replacement parts is the paramount consideration (and manufacturer is the sole supplier).
2. Where a sole supplier's item is needed for trial use or testing.
3. Where a sole supplier's item is to be required when no other item will service the needs of UMMC.

## Schedule

Task	Date
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First Advertisement Date	November 28, 2016
Second Advertisement Date	December 5, 2016
Response Deadline from Objectors	December 12, 2016, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before March 17, 2016

## Project Details

**1. Describe the commodity that the agency is seeking to procure:**

The University of Mississippi Medical Center (UMMC) is seeking to the Volcano Intravascular Ultrasound (IVUS) Catheters and disposables associated with the Volcano CORE Mobile and s5 Imaging Systems as a sole source from Volcano, a division of Philips.

The IVUS systems along with its proprietary disposables are utilized by surgeons to view images of diseased vessels from inside the artery. The IVUS systems display comprehensive, colorized images of the four plaque component categories: fibrous, fibrofatty, dense calcium, and the necrotic core. These images give the provider valuable information regarding the interior structures of the vessels that cannot be seen using any other technology.

**2. Explain why the commodity is the only one (1) that can meet the needs of the agency:**

Volcano's proprietary system technology provides accurate measurements of vessels and lumen size, plaque area and volume, and the locality of vital anatomical makers. The Volcano products are the only ones that offer both Fractional Flow Reserve (FFR) as well as Instantaneous Wave Free Ratio (iFR). Also, the Volcano catheters provide centimeter markers to expedite low contrast procedures, softer tips with lower entry profile, and GlyDx hydrophilic coating for delivery through convoluted anatomy.

**3. Explain why the source is the only person or entity that can provide the required commodity:**

Volcano, a division of Philips, is the sole manufacturer and distributor of the IVUS catheters and associated disposables. See supporting letter from **Volcano**, Attachment A.

**4. Explain why the amount to be expended for the commodity is reasonable:**

The estimated amount to be expended for the purchase of the **Volcano Intravascular Ultrasound Catheters and associated disposables** over the term of the placement agreement is \$450,000.

**5. Describe the efforts that the agency went through to obtain the best possible price for the commodity:**

Through market intelligence, UMMC was able to negotiate best pricing for these products. All applicable discounts were explored and applied.

## **Submission Instructions and Format of Response from Objecting Parties**

Interested parties who have reason to believe that the **Volcano Coronary Intravascular Ultrasound Catheters, Volcano Peripheral Intravascular Ultrasound Catheters, Fractional Flow Reserve Pressure Guide Wires, and Phoenix Atherectomy Systems** (hereafter, “Products”) should not be certified as a sole source should provide information in the Vendor Form for the State to use in determining whether or not to proceed with awarding the sole source to **Volcano, a division of Philips**. The Vendor Form may be found at <http://www.dfa.state.ms.us/Purchasing/documents/ObjectiontoSoleSourceDetermination.pdf>.

Objections must include the certification in Attachment B.

Comments will be accepted at any time prior to Monday, December 12, 2016, at 3:00 p.m. (Central Time) to [solesource@umc.edu](mailto:solesource@umc.edu). Responses may be delivered via email to [solesource@umc.edu](mailto:solesource@umc.edu). UMMC WILL NOT BE RESPONSIBLE FOR DELAYS IN THE DELIVERY OF RESPONSES. It is solely the responsibility of the Interested Parties that responses reach UMMC on time. Responses received after the deadline and responses that lack all required information will be rejected. UMMC reserves the right to inspect Interested Party’s commodity for comparison purposes.

If you have any questions concerning the information above or if we can be of further assistance, please contact [solesource@umc.edu](mailto:solesource@umc.edu).

Attachment A: Vendor Correspondence

Attachment B: Objection Certification



November 10, 2016

University of Mississippi Medical Center  
2500 North State Street  
Jackson, MS 39216

Dear Sir or Madam:

Philips/ Volcano is the sole proprietor and manufacturer of digital, Phased Array Intravascular Ultrasound ("IVUS") for both Coronary and Peripheral applications. In addition to digital, Phased Array IVUS, Philips/Volcano also offers a Rotational Coronary IVUS catheter on the CORE system. These two IVUS technologies are available on both the CORE Mobile and Integrated platforms. No other commercially available platform offers both on the same platform, and no other company offers digital, Phased Array IVUS in any form.

Philips/Volcano has the broadest portfolio of Peripheral Phased Array IVUS catheters with the largest imaging diameters capable of imaging up to 60mm. No other company offers Peripheral Phased array IVUS technologies.

In addition to these technologies, the CORE system offers Fractional Flow Reserve ("FFR") as well as Instantaneous Wave Free Ratio ("iFR"). Both of these technologies are FDA approved for documentation of Coronary ischemia. Philips/Volcano is the sole proprietor for iFR technology. The iFR technology provides a hyperemic free measurement assessment for ischemia – much like FFR, but without the need to administer a hyperemic agent.

Lastly, Philips/Volcano is the sole proprietor of Chromaflo and Virtual Histology ("VH") imaging. These are both software applications available on the CORE system. Chromaflo imaging highlights blood flow inside the vessel for easy assessment of stent apposition, lumen size, and more. Virtual Histology uses advance spectral analysis to classify Coronary plaques into four tissue types. Both of these technologies can be accessed with the touch of a button, and both are only available from Philips/Volcano.

For the products listed above, University of Mississippi Medical Center is unable to purchase from any other vendor.

Should you have any questions at all, please do not hesitate to contact me at (205) 789-9367. We at VOLCANO look forward to a long and mutually beneficial relationship.

Best regards,

A handwritten signature in black ink, appearing to read "K. Fisher".

Kevin Fisher  
Territory Manager

Attachment B

**SUBMITTED IN RESPONSE TO  
Sole Source Certification No. SS5062  
Accepted until December 12, 2016, at 3:00 p.m.**

I certify that the information contained in this objection is true and accurate to the best of my knowledge. I understand that UMMC will investigate all statements made in this objection and that any false or misleading information provided may result in adverse action.

\_\_\_\_\_  
Objector Name  
Objector's title

\_\_\_\_\_  
Date