

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: March 7, 2016

Re: Sole Source Certification Number **SS5003** for **DiamondBack Orbital Atherectomy System**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5003** for **DiamondBack Orbital Atherectomy System**, please be advised that UMMC intends to award the purchase of the **DiamondBack Orbital Atherectomy System** to **Cardiovascular Systems Inc.** as the sole source provider of the **DiamondBack Orbital Atherectomy System**.

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
First Advertisement Date	March 7, 2016
Second Advertisement Date	March 14, 2016

Response Deadline from Objectors	March 24, 2016, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before May 20, 2016

Project Details

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

The Cardiac Catheterization Department of University of Mississippi Medical Center (UMMC) Grenada is looking at purchasing the DiamondBack Peripheral Orbital Atherectomy System from Cardiovascular Systems Inc.

The Diamondback system revascularizes heavily calcified vessels. The Orbital Atherectomy System will ultimately increase the physicians' ability to provide safer and effective treatment to patients with complex peripheral arterial disease.

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

The unique, orbital motion of the Diamondback device provides exclusive features designed to optimize procedural safety and efficacy for patients suffering from occlusive peripheral arterial disease (PAD). The majority of the cases seen at UMMC Grenada have a high focus on infra popliteal disease. Also, this is the only device with a four (4) French sheath that treats calcium and establishes straight line flow to the foot.

The products that are associated with this system would be the Diamondback Catheters and Viperwires. These particular supplies are only used with the Peripheral Orbital Atherectomy no other guidewire can be used with this system. The Viperwires has good push ability and torque response. The diamondback catheters does require the use of this proprietary guidewire.

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

This product is not available from any other manufacturer or distributor. Cardiovascular Systems Inc. states that they do not have any other distributors and work through a direct sales organization of their own. Cardiovascular Systems Inc. does have patent on this system and items. See supporting letter from **Cardiovascular Systems Inc.**, Attachment A.

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

The estimated amount to be expended is for the purchase of the DiamondBack Orbital Atherectomy System is \$3,842,280.00. This amount is within the expected price range for these products and the number of cases to be performed.

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 **DiamondBack Orbital Atherectomy System** (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 **Cardiovascular Systems Inc.** 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 Thursday, March 24, 2016, at 3:00 p.m. (Central Time) to solesource@umc.edu. Responses may be delivered via email to 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.

Attachment A: Vendor Correspondence

Attachment B: Objection Certification

"Attachment A"

September 22, 2015

UMC Grenada
Attn: Danny Cain
960 Avent Drive
Grenada, MS 38901

Dear Danny:

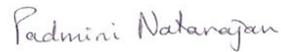
This certifies that Cardiovascular Systems, Inc is the sole supplier of the Orbital Atherectomy System, also known as the DiamondBack. The product names associated with the system are the DiamondBack Catheters and ViperWires.

We are the manufacturer of these products and are the sole supplier of the same. The company is headquartered in St. Paul, MN. We do not have any distributors and work through a direct sales organization of our own employee salespeople.

Please contact me if you need any further information or clarification.

Thank you for your interest in Cardiovascular Systems, Inc products.

Sincerely,



Padmini Natarajan
Padmini Natarajan
Senior Director, Customer Operations
Tel: 877-274-0901
pnatarajan@csi360.com

Attachment B

**SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS5003
Accepted until March 24, 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