

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: May 4, 2017

Re: Sole Source Certification Number **SS5095** for **Impella Circulatory Support Catheters and Accessories**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5095** for **Impella Circulatory Support Catheters and Accessories**, please be advised that UMMC intends to award the purchase of the **Impella Circulatory Support Catheters and Accessories** to **Abiomed, Inc.** as the sole source provider of the **Impella Circulatory Support Catheters and Accessories**.

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	May 4, 2017
Second Advertisement Date	May 11, 2017

Response Deadline from Objectors	May 18, 2017, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before August 18, 2017

Project Details

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

The University of Mississippi Medical Center (UMMC) seeks to purchase Impella Circulatory Support catheters and accessories that correspond to the Impella AIC Systems already owned by UMMC.

The Impella system is a FDA cleared percutaneous ventricular assist device designed to provide a patient's heart hemodynamic support. The consumables include a catheter-type device that is inserted through the femoral artery and placed in the patient's heart. Once activated, it assists the heart by moving blood from the heart and circulating it to the rest of the body. This decreases the workload of the heart in patients with hemodynamic instability.

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

UMMC currently owns two Impella AIC Systems, and the catheters and accessories provided by Abiomed for the Impella system are proprietary in nature to this system. There are no other devices that will function with this equipment.

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

Abiomed, Inc. is the sole manufacturer and distributor of the Impella Circulatory Support Catheters and Accessories. See supporting letter from **Abiomed, 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 **Impella Circulatory Support Catheters and Accessories** is \$1M for the term of the contract. This amount is within the expected price range for these products.

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 **Impella Circulatory Support Catheters and Accessories** (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 **Abiomed, 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, May 18, 2017, 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



April 26, 2017

Mr. Thomas Wills, MPPM, BSN, RN
Executive Director University Heart Services
University of Mississippi Medical Center
2500 N. State Street
Jackson, MS 39216

Dear Mr. Wills:

Per your request to Ryan Sisson, Abiomed's Account Manager for UMMC, below you will find information with regard to Impella® functionality and sole source status.

The Impella® family of catheters are percutaneous heart pumps that actively unload the left ventricle, allowing the heart muscle to rest while perfusing the end organs such as the kidneys and brain. No other product provides this type of heart support, and Impella® is the only FDA approved therapy indicated for the use in PCI for high risk patients or in AMI Cardiogenic shock.

Treatment with percutaneous coronary intervention (PCI) for high risk patients in need of hemodynamic support should only be done with an FDA indicated therapy with demonstrated safety and efficacy. In AMI cardiogenic shock, patients arrive in an emergency setting and need immediate care. Clinical studies have demonstrated improved survival and native heart recovery when Impella® support is initiated pre-PCI and in the cath lab. Only the Impella® family of products can be utilized in this fashion.

The Impella® family of products and services are only available from Abiomed, Inc. and are not available through resellers.

Please let us know if we can provide any additional information. Thank you for your continued support and interest in Abiomed and our Impella® product lines.

Kind regards,

Michael G. Howley
Vice President and General Manager, Global Sales

Attachment B

**SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS5095
Accepted until May 18, 2017, 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