

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: December 7, 2015

Re: Sole Source Certification Number **SS5002** for **Tyshak NuCLEUS and NuCLEUS-X catheters**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5002** for **Tyshak NuCLEUS and NuCLEUS-X catheters**, please be advised that UMMC intends to award the purchase of the **Tyshak NuCLEUS and NuCLEUS-X catheter** to **B. Braun** as the sole source provider of the **Tyshak NuCLEUS and NuCLEUS-X catheters**.

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	December 7, 2015
Second Advertisement Date	December 14, 2015

Response Deadline from Objectors	December 17, 2015, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before December 18, 2015

Project Details

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

The University of Mississippi Medical Center's Department of Pediatric Cardiac Catheterization Laboratory is requesting the purchase of Tyshak NuCLEUS and NuCLEUS-X balloon catheters. Both are percutaneous transluminal balloon catheters one being a low profile whereas the latter is a larger (high pressure) profile.

The Tyshak NuCLEUS and NuCLEUS-X design features a single dilation on a coaxial catheter shaft which contributes to columnar strength for optimal push ability and trackability through tortuous anatomy. The outer body is made of polymeric tubing, and the inner tubing is comprised of a multi-layer extrusion of polyamide that surrounds a braid of 304 LV Stainless Steel. These balloons feature a smaller 'waist' segment at its midpoint to facilitate locking into the valve or other area of stenosis. This 'waist' area will expand to 90% of the rated balloon diameter upon injection of the inflation volume. The distal lumen terminates at the tip of the catheter and will accept the passage of the 0.035" guidewire. The Tyshak NuCLEUS and NuCLEUS-X also has a kink resistant shaft and contains 3 radiopaque platinum marker bands. With its quick inflation and deflation times, it minimizes procedure times while maximizing reperfusion.

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

The Pediatric Cardiac Catheterization Laboratory treats very complex congenital anomalies. The design of the Tyshak NuCLEUS and NuCLEUS-X would grant us more effective results in our balloon dilations.

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

B.Braun is the only vendor who offers balloon catheters designed with a waist formed at the midpoint. The Tyshak NuCLEUS and NuCLEUS-X balloon catheters are not available domestically from any other distributor or reseller. See supporting letter from **B. Braun**, 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 Tyshak NuCLEUS and NuCLEUS-X catheters is \$16,000. 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 **Tyshak NuCLEUS and NuCLEUS-X catheters** (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 **B. Braun**. 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, December 17, 2015, 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"



B. Braun Interventional Systems Inc.
824 Twelfth Avenue
Bethlehem, PA 18018 USA
Tel: 1-877-VENA CAV (836-2228)
Fax: 610 849-1334
www.bisusa.org

September 29, 2015

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

Thank you for providing B. Braun Interventional Systems Inc. ("BIS") with the opportunity to present an informational response to your request for University of Mississippi Medical Center regarding the Tyshak NuCLEUS™ catheter.

There are other manufacturers of Valvuloplasty type balloons; however, proprietary materials and proprietary manufacturing techniques result in a clinically preferred product vs. competitive devices. The uniquely designed, smaller waste segment of the balloon at its midpoint facilitates catheter locking into the valve area being dilated, allowing accurate balloon placement for the user. The balloons low profile design provides the user the ability to utilize a reduced sheath size for vascular access, minimizing entry site complications. There is no patent on the product, but trade secret manufacturing processes and proprietary materials of construction are unique to this product design, resulting in its sound clinical performance. BIS is the exclusive distributor of this device in the United States.

This response contains confidential and proprietary information of BIS and is submitted with the understanding that you will keep the information hereof confidential and shall not disclose or use such information for any purpose other than for evaluation of our product.

Thank you for the opportunity to submit a response to your request. Additional information regarding BIS may be obtained through our web site, www.bisusa.org. Should you have any questions concerning any part of our response, please contact your BIS Sales Representative, Teresa Deitz (615) 714-5423.

Sincerely,

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

Dave Mittl
Corporate Director New Business Development
B. Braun Interventional Systems Inc.

Attachment B

**SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS5002
Accepted until December 17, 2015, 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