

# Notice of Intent to Certify Sole Source

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**To:** Interested Parties

**From:** Stacy Baldwin  
Agency Procurement Officer

**Date:** July 11, 2016

**Re:** Sole Source Certification Number **SS5041** for **EKOS Ekosonic Endovascular systems and catheters**

**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 **SS5041** for **EKOS Ekosonic Endovascular systems and catheters**, please be advised that UMMC intends to award the purchase of the **EKOS Ekosonic Endovascular systems and catheters** to **EKOS Corporation** as the sole source provider of the **EKOS Ekosonic Endovascular systems and 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

<b>Task</b>	<b>Date</b>
First Advertisement Date	July 11, 2016
Second Advertisement Date	July 18, 2016

Response Deadline from Objectors	July 25, 2016, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before August 22, 2016

## Project Details

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

The University of Mississippi Medical Center (UMMC) seeks to purchase EKOS Ekosonic Endovascular systems and catheters.

The EKOS ultrasonic devices are designed to gently accelerate the penetration of thrombolytic agents into thrombus, providing high levels of lysis. These devices provide faster, safer and more complete dissolution of thrombus.

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

It is the only minimally invasive endovascular therapy approved to treat Pulmonary Embolism. EKOS uses high frequency low energy ultrasound to reversibly change the structure of fibrin within the clot. The ultrasound plays two roles. The frequency we use, 2.2mgHz thins and separates the fibrin strands exposing the plasminogen receptor sites which are embedded in the thrombus. The second role of the ultrasound is to transport medications via acoustic streaming. The combined effect of these two functions of the ultrasound are to saturate the thrombus with TPA. This results in rapid lysis of the thrombus and reversal of RV dysfunction.

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

EKOS Corporation is the sole manufacturer and distributor of the EKOS Ekosonic Endovascular systems and catheters. See supporting letter from **EKOS Corporation**, Attachment A.

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

The control units will be placed at UMMC with a minimum number of catheters to be purchased. The price of the catheters covers the costs of the devices placement. The estimated amount to be expended is for the purchase of the **EKOS Ekosonic Endovascular systems and catheters** is \$200,000. 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 **EKOS Ekosonic Endovascular systems and 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 **EKOS Corporation**. 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, July 25, 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



A BTG International group company

June 17, 2016

To Whom it May Concern:

**Subject: EKOS Sole Source for EKOS EkoSonic® Endovascular System with Rapid Pulse Modulation™**

The EKOS EkoSonic® Endovascular System with Rapid Pulse Modulation™ is the only ultrasound-enhanced thrombolysis catheter available on the market. This technology decreases the time required to dissolve blood clots in both arteries and veins by using 2.2 MHz ultrasound energy delivered through the center of the catheter. The ultrasound energy affects the clot by making the clot more permeable to the thrombolytic drug<sup>1,2</sup> and also uses acoustic energy to drive drug into the clot. The effect is fully reversible and does not break or fragment the fibrin matrix. This technology is covered by US patents and is not available to any other manufacturers or in any other products. EKOS Corporation is the sole manufacturer and sole distributor of the devices.

FDA CLEARED INDICATIONS: The EkoSonic® Endovascular System is indicated for the ultrasound facilitated, controlled and selective infusion of physician-specified fluids, including thrombolytics, into the vasculature for the treatment of pulmonary embolism; the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature; and the infusion of solutions into the pulmonary arteries. Instructions for Use, including warnings, precautions, potential complications, and contraindications can be found at [www.ekoscorp.com](http://www.ekoscorp.com). Caution: Federal (USA) law restricts these devices to sale by or on the order of a physician.

References:

1. Atar S, Luo H, Nagai T, et al. Arterial thrombus dissolution in vivo using a transducer-tipped, high-frequency ultrasound catheter and local low-dose urokinase delivery. *J Endovasc Ther.* 2001;8:282-290.
2. Braaten JV, Goss RA, Francis CW. Ultrasound reversibly disaggregates fibrin fibers. *Thromb Haemost.* 1997;78:1063-1068.

Please call me if you have any questions or concerns and thank you for allowing our sales personnel to support EKOS technology in your institution.

Sincerely,

A handwritten signature in cursive script that reads "Denise Edwards".

Denise Edwards  
Clinical Manager  
[denise.edwards@ekoscorp.com](mailto:denise.edwards@ekoscorp.com)

Attachment B

**SUBMITTED IN RESPONSE TO  
Sole Source Certification No. SS5041  
Accepted until July 25, 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