

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: October 1, 2015

Re: Sole Source Certification Number SS0009 for Integra CUSA Excel Ultrasonic Surgical Aspirator accessories, consumables, and tips

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number SS0009 for Integra CUSA Excel Ultrasonic Surgical Aspirator accessories, consumables, and tips, please be advised that UMMC intends to award the purchase of the Integra CUSA Excel Ultrasonic Surgical Aspirator accessories, consumables, and tips to Integra Life Sciences Corporation as the sole source provider of the Integra CUSA Excel Ultrasonic Surgical Aspirator accessories, consumables, and tips.

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	October 1, 2015

Second Advertisement Date	October 8, 2015
Response Deadline from Objectors	October 15, 2015, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before October 15, 2015

Project Details

The University of Mississippi Medical Center (UMMC) wishes to purchase Integra CUSA Excel Ultrasonic Surgical Aspirator accessories, consumables and tips that correspond to the CUSA Aspirator already owned by UMMC.

The CUSA Aspirator is used by surgeons to provide ultrasonic tissue ablation during procedures. The variety of tips and handpieces offered by CUSA allows the surgeon to customize their aspiration approach depending upon patient and/or situational needs. Feedback elicited through the handpieces enables the surgeon to differentiate between tissue types to assist with safety within the procedure. The CUSA system also provides the capability for the surgeon to control bleeding during tissue removal without having to use another instrument.

The University of Mississippi Medical Center currently owns the CUSA Excel Ultrasonic Surgical Aspirator System, and the accessories and tips provided by Integra for the CUSA system are proprietary in nature to this system. There are no other devices that will function with this equipment.

Integra manufactures the CUSA system and the proprietary components and disposables for proper use of the aspirator system. Integra is the sole manufacturer and supplier of the CUSA Excel system. They are not available from any other distributor. See supporting letter from Integra Life Sciences Corporation, Attachment A.

The estimated amount to be expended is for the purchase of the Integra CUSA Excel Ultrasonic Surgical Aspirator accessories, consumables and tips is \$80,000. This amount is within the expected price range for these products.

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 Integra CUSA Excel Ultrasonic Surgical Aspirator accessories, consumables, and tips (hereafter, "Products") should not be certified as a sole source should provide information in the following format for the State to use in determining whether or not to proceed with awarding the sole source to Integra Life Sciences Corporation.

1.1 Interested Party Information

- 1.1.1 Company Name and Address
- 1.1.2 Contact Name, Phone Number, and Email Address
- 1.1.3 Company Website URL, if applicable
- 1.2 Objection to Sole Source Certification
 - 1.2.1 Interested parties must present specific objections to the sole source certification, including, but not limited to, the following:
 - 1.2.1.1 A detailed explanation of why Interested Party believes the purchase of the Products is not a sole source procurement.
 - 1.2.1.2 If Interested Party claims a comparable product exists, the objection must contain:
 - 1.2.1.2.1 A description of the commodity that Interested Party believes is comparable to the Products;
 - 1.2.1.2.2 An explanation of why Interested Party's commodity can also meet the needs of the agency; and
 - 1.2.1.2.3 A list of sources from which Interested Party's commodity may be procured.
 - 1.2.1.3 If Interested Party claims that the Products are available from a source other than Integra Life Sciences Corporation, the objection must contain:
 - 1.2.1.3.1 A written statement from Integra Life Sciences Corporation that Interested Party is an authorized distributor or reseller of the Products.
 - 1.2.1.4 A statement regarding the Interested Party's capabilities as related to this sole source certification.
- 1.3 Objections must include the certification in Attachment B.
- 1.4 Comments will be accepted at any time prior to Thursday, October 15, 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



September 18, 2015

Subject: Sole Source Provider Status

- **CUSA® Excel+ Ultrasonic Tissue Ablation System**

Dear Valued Customer:

The above subject products are manufactured by or for Integra Life Sciences Corporation. Integra is the sole source provider of these products.

Since the introduction of the CUSA NS100 in 1977, the CUSA name has been associated with premium quality and technological sophistication in ultrasonic surgical aspiration. The CUSA Excel+ offers several unique features such as the Tissue Select® Safety Setting and the CEM™ module for hemostasis.

Tissue Select is a safety setting unique to the CUSA Excel that allows the surgeon to increase selectivity and safety without sacrificing procedure speed.

The CUSA Electrosurgery Module (CEM™) nosecone provides the surgeon with a powerful combination of electrosurgery and ultrasonics in one handpiece, allowing the surgeon to control bleeding during tissue removal without having to use a second instrument. The CUSA Excel system is the only ultrasonic tissue ablation system to incorporate simultaneous electrosurgical and ultrasonic capabilities with the press of a button.

For more information on these exclusive functionalities, please see the attached brochure or contact your local Integra sales representative.

Sincerely,

A handwritten signature in blue ink, appearing to read "Kayne Ryan". The signature is fluid and cursive, with a long horizontal stroke at the end.

Kayne Ryan
Global Senior Product Manager
Integra Life Sciences Corporation

Attachments: CUSA Excel+ Brochure 0103221-3 © 2013

PMAP No.: 0388986-1

Attachment B

**SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS0009
Accepted until September 24, 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