

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: January 12, 2017

Re: Sole Source Certification Number **SS5073** for **Visica 2 System and associated disposables**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5073** for **Visica 2 System and associated disposables**, please be advised that UMMC intends to award the purchase of the **Visica 2 System and associated disposables** to **Sanarus Technologies, Inc.** as the sole source provider of the **Visica 2 System and associated disposables**.

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	January 12, 2017
Second Advertisement Date	January 19, 2017

Response Deadline from Objectors	January 27, 2017, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before February 24, 2017

Project Details

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

The University of Mississippi Medical Center (UMMC) seeks to purchase the Visica 2 System and associated disposables as a sole source from Sanarus Technologies, Inc.

The Visica 2 Treatment System is an image-guided device that freezes the tumor and benign lesions such as fibroadenomas of the breast, thereby destroying it and preventing regrowth. The procedure, known as the Visica® Procedure, offers patients a minimally invasive alternative to treatments such as lumpectomy. The procedure requires only local anesthesia in the office or hospital setting allowing for quicker recovery time.

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

The Visica 2 System is the only cryoablation system that utilizes a single cryo probe per lesion. It only requires a 3 mm incision regardless of the tumor size which conserves the breast shape. This technology is exclusive to Sanarus. This will allow UMMC to provide their patients with a far less invasive alternative for treatment as well as better cosmetic results, shorter procedure time, and faster recovery.

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

Sanarus is the sole manufacturer of the Visica 2 System and associated disposables. They are not available from any other distributor. See supporting letter from **Sanarus Technologies, Inc.**, Attachment A.

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

The Visica 2 System will be placed at UMMC with a minimum number of disposables to be purchased. The estimated amount to be expended is for the purchase of the **Visica 2 System and associated disposables** is \$200K. 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 **Visica 2 System and associated disposables** (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 **Sanarus Technologies, 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 Friday, January 27, 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



December 5, 2016

Dear Sir or Madam,

Re: Cryoablation System at the University of Mississippi

The Visica® system was designed to provide a minimally invasive procedure allowing physicians with ultrasound skills to perform cryoablation within the office or hospital setting. Sanarus is the sole manufacturer and distributor of the Visica® 2 cryoablation system. Visica is a liquid nitrogen based cryo surgical unit that is composed of two parts, the first being the cryo generator and the second being the cryo probe. Liquid nitrogen achieves colder temperatures than that of the conventional argon based cryoablation systems. Visica is the only cryoablation system that uses a single cryo probe per lesion.

Numerous clinical articles have been published on the effectiveness of cryo surgery. Specifically, the NCI sponsored Z1072 trial using exclusively Visica 2 showed that when targeting breast lesions less than 2.0 cm, 92% of the lesions had total necrosis within the ablation zone and 100% for necrosis for those ≤ 1.0 cm.¹

The system is easy to use and on-site training is provided with the acquisition of the product. Marketing and advertising support is also available upon request to help ensure local market awareness. The Visica 2 system is 510(K) cleared by the FDA for the ablation of malignant tissue and benign tumors providing an alternative to traditional surgery for both patients and clinicians.

Thank you for considering the acquisition of the Visica 2 treatment system. If there are any questions or concerns, please contact me directly at mnalipinski@sanarus.com or the phone number listed below.

Sincerely,

Matt Nalipinski
COO/CTO
Sanarus Technologies Inc.
1249 Quarry Lane, Ste 150
Pleasanton, CA 94566
925-460-6080

¹ R Simmons et al, A Phase II Trial Exploring the Success of Cryoablation Therapy in the Treatment of Invasive Breast Carcinoma: Results from ACOSOG (Alliance) Z1072, Ann Surg Oncol, May 2016, DOI 10.1245/s10434-016-5275-3

Attachment B

**SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS5073
Accepted until January 27, 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