Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin Agency Procurement Officer

Date: February 22, 2016

Re: Sole Source Certification Number SS5014 for MedWaves Microwave Ablation System and Antennas

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5014** for **MedWaves Microwave Ablation System and Antennas**, please be advised that UMMC intends to award the purchase of the **MedWaves Microwave Ablation System and Antennas** to **Classic Medical, Inc.** as the sole source provider of the **MedWaves Microwave Ablation System and Antennas**.

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	February 22, 2016
Second Advertisement Date	February 29, 2016

1 0	March 7, 2016, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before May 20, 2016

Project Details

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

The University of Mississippi Medical Center (UMMC) seeks to purchase the MedWaves Microwave Ablation System and Antennas.

Microwave Ablation Systems are used to destroy or ablate diseased soft-tissue by heating the tissue to a temperature that causes cell death. Heating of the tissue takes place because the microwave energy causes the water molecules in the diseased soft-tissue to rotate. This rotation of the water molecules causes friction, which in turn causes the tissue to heat up. The generator produces microwave energy which is transmitted through the antennas and into the patient. MedWaves utilizes temperature and frequency based feedback mechanisms to enable precise and safe control over the delivery of microwave energy in biomedical applications by allowing the customization of the ablation zones.

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

MedWaves is the only company that provides the small burn-zone antennas in more than 15 cm length, and is the only company in the market that provides a flexible tip antenna which is more than 30 cm in length. This is critical for treatment planning of ablations within the spine.

MedWaves is the only company on the market that can do any size ablation with only one antenna versus two to three from other vendors, providing a more cost effective approach for treatment. Also, these are the only antennas that are compatible with Magnetic Resonance Imaging (MRI). This system will provide our bone cancer patients with a minimally invasive option for treatment and spare the need for extensive surgical procedures.

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

Classic Medical, Inc. is the only company that represents and distributes the MedWaves Microwave Ablation System and proprietary antennas in Mississippi. See supporting letter from **Classic Medical, Inc.**, Attachment A.

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

This system will be placed in Interventional Radiology with a minimum number of disposables to be purchased. The price of the disposables covers the cost of the system's placement. The estimated amount to be expended for the purchase of the MedWaves Microwave Ablation System and Antennas is \$250,000.

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 **MedWaves Microwave Ablation System and Antennas** (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 **Classic Medical, Inc**. The Vendor Form may be found at <u>http://www.dfa.state.ms.us/Purchasing/documents/ObjectiontoSoleSourceDetermination.pdf</u>.

Objections must include the certification in Attachment B.

Comments will be accepted at any time prior to Monday, March 7, 2016, at 3:00 p.m. (Central Time) to <u>solesource@umc.edu</u>. Responses may be delivered via email to <u>solesource@umc.edu</u>. 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 <u>solesource@umc.edu</u>.

Attachment A: Vendor Correspondence Attachment B: Objection Certification



16760 W Bernardo Dr San Diego, Ca 92127 Tel: 858-946-0015 www.medwaves.com

January 26, 2016

Memorandum: Relationship between Classic Medical, Inc. and MedWaves, Inc.

Classic Medical Incorporated with its business located at 2116 S.E. Rays Way, Stuart, FL 34994 is the exclusive distributor and representative for MedWaves' products within the state of Mississippi, USA. MedWaves manufactures and markets its AveCure[™] Microwave Coagulation-Ablation system worldwide. The system comprises of durable microwave power generator(s) and assortment of single-patient-use microwave antennas and extension-cables.

Best regards,

min Ted Ormsby President/CEO

SUBMITTED IN RESPONSE TO Sole Source Certification No. SS5014 Accepted until March 7, 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