

# Notice of Intent to Certify Sole Source

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**To:** Interested Parties

**From:** Stacy Baldwin  
Agency Procurement Officer

**Date:** October 27, 2016

**Re:** Sole Source Certification Number **SS5055** for NueWave Certus 140 Ablation System and probes

**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 **SS5055** for NueWave Certus 140 Ablation System and probes, please be advised that UMMC intends to award the purchase of the NeuWave Certus 140 Ablation System and probes to NeuWave Medical as the sole source provider of the NeuWave Certus 140 Ablation System and probes.

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	October 27, 2016
Second Advertisement Date	November 3, 2016

Response Deadline from Objectors	November 10, 2016, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before November 11, 2016

## Project Details

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

The University of Mississippi Medical Center (UMMC) seeks to purchase NueWave Certus 140 Ablation System and probes to provide ablation of larger liver tumors that is currently not possible with single probe systems. Ablation is the only known non-resective curative therapy for both primary and metastatic tumors of the liver. Using a single probe for multiple ablations of a large tumor creates unpredictable ablation zones and the opportunity for missed areas of tumor and early recurrence. The Certus 140 System also provides ability for pre-coagulation of the liver transection margin during liver resections. The multi-probe ability of this system allows for more rapid pre-coagulation of the resection plane and thus shorter operative times. Pre-coagulation of liver resection planes provides the opportunity for reduced blood loss during hepatic surgery and, in turn, reduced blood product usages. Blood transfusion during hepatic resection is a well described contributor to increased length of stay post operatively as well as cancer recurrence following resection.

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

NeuWave Certus is the only microwave system that allows for:

- 1) Multi-probe ablation of liver tumors thus allowing for synchronized ablation of larger liver tumors.
- 2) Synchronized multi-probe ablation allows for a calibrated ablation zone to ensure predictable coverage of tumors rather than relying on provider estimation of overlap using a single probe, multiple subsequent ablations.
- 3) NeuWave Certus 140 utilizes CO2 cooled probes allowing us to use smaller probes to achieve similar ablation zones with less trauma to surrounding tissues.
- 4) The Tissue-Loc™ feature ensures the probe stays within the intended target rather than migrating due to tumor destruction as the ablation proceeds.
- 5) Has the highest power output resulting in shorter ablation times and shorter operative times.
- 6) Offers ablation confirmation ability in procedure, to ensure tumor coverage and complete treatment.
- 7) Has the ability to ablate liver tumors up to 7cm. Other systems are limited to tumor size  $\leq$  5cm.

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

NeuWave Medical is the sole provider of the Certus 140 system and proprietary probes. They are not available from any other distributor. See supporting letter from NeuWave Medical, 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 NueWave Certus 140 Ablation System and probes is \$220,000 for system and commodities. The pricing for this system and commodities is in line with the lowest pricing around the county.

**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 NueWave Certus 140 Ablation System and probes (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 NeuWave Medical. 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, November 10, 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

## Attachment A



October 3, 2016

Michelle Spera, MSN RN  
Strategic Sourcing Manager  
Supply Chain Management  
University of Mississippi Medical Center  
2500 North State Street  
Jackson, MS 39216

RE: Sole Source Distribution

Dear Ms. Spera,

NeuWave Medical is the Sole Provider of the Certus 140 System and unique family of Probes. Our **Certus 140 2.45GHz Intelligent Ablation System** is the only gas-cooled (CO<sub>2</sub>), high-power(195W), 17ga, phased, single or multi-probed ablation system on the market. Our **Precision PR Probe** is the only probe on the market with distal energy control, in which ablation encompasses the tip and then burns proximal, allowing precision ablation. We are also the only provider of **"tissue tuned" probes for the liver, kidney and lung**. Our **CO<sub>2</sub>/gas-cooled probes with Tissu-Loc** reduce probe migration, and allow the physician to "freeze" probe in place, and is a unique feature to the Certus 140. Our **17ga** probe is the smallest on the market and a significant advantage over the standard 13ga probes. Exclusive to our platform, we offer **one (1), two (2), or three (3) probe capability, independently controlled** with high power  $\leq$ (195W), **PHASED 2.45GHz** microwave energy, which provides our customer with the unique ability to ablate very large lesions in a controllable fashion. We are also the only platform to support **additional surgical application - Pre Transection Coagulation for resection** with the distal energy control of the PR Probe. Lastly, we are now the only company with a computer controlled software platform that provides **intra-procedural feedback** with our, **first to market Ablation Confirmation Software**.

NeuWave Medical products are manufactured, tested and distributed from our corporate office in Madison Wisconsin.

Regards,



Mike Blue  
Vice President, Sales  
NeuWave Medical Inc.

NEUWAVE MEDICAL | 3529 ANDERSON STREET | MADISON WI | 877-323-9283 | WWW.NEUWAVE.COM

Attachment B

**SUBMITTED IN RESPONSE TO  
Sole Source Certification No. SS5055  
Accepted until Thursday, November 10, 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