

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: March 7, 2016

Re: Sole Source Certification Number **SS5000** for **Inspire Medical Systems Inc. Upper Airway Stimulation System**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5000** for **Inspire Medical Systems Inc. Upper Airway Stimulation System**, please be advised that UMMC intends to award the purchase of the **Upper Airway Stimulation System** to **Inspire Medical Systems Inc.** as the sole source provider of the **Upper Airway Stimulation System**.

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	March 7, 2016
Second Advertisement Date	March 14, 2015

Response Deadline from Objectors	March 24, 2015, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before March 30, 2016

Project Details

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

The University of Mississippi Medical Center, Department of Otolaryngology, is requesting purchase authority for Inspire Medical Systems, Inc. Upper Airway Stimulation System to provide additional treatment options to the obstructive sleep apnea (OSA) patient population. This treatment is an option for some patients by way of hypoglossal nerve stimulation, before resorting to an anatomy altering surgery.

The Inspire Upper Airway Stimulation (UAS) system is an implantable nerve stimulator used to treat moderate to severe OSA. The Inspire UAS system consists of implanted components including the implantable pulse generator (IPG), stimulation lead, and sensing lead and external components including the physician programmer and the patient programmer (sleep remote). The IPG detects the patient's breathing pattern and maintains an open airway with mild stimulation of the hypoglossal nerve, which controls tongue movement, during inhaled breathing. The physician adjusts the stimulation settings using the external physician programmer. The patient sleep remote allows the patient to turn therapy on before they go to sleep and to turn therapy off when they wake up.

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

There is no other therapy available that controls OSA in the same manner as the hypoglossal nerve stimulator from Inspire Medical Systems, Inc. Once a patient fails continuous positive airway pressure (CPAP), or medical therapy, the other options consist of invasive anatomy changing surgery which may or may not be effective. Inspire UAS provides the patient an alternative.

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

Inspire Medical Systems is the sole manufacturer and distributor of the only FDA approved implantable neuro-stimulator to treat moderate to severe OSA, for those patients who do not tolerate CPAP. The system cannot be purchased through any other entity. See supporting letter from **Inspire Medical Systems Inc.**, 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 **Upper Airway Stimulation System** is \$658,275. 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 **Upper Airway Stimulation System** (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 **Inspire Medical Systems 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 Thursday, March 24, 2016, 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

Attachment A



April 27, 2015

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

RE: Sole Source/Vendor Justification Letter

Dear Ms. Spera:

Inspire Medical Systems, Inc. manufactures and sells the only FDA-Approved (PMA, April, 2014), and fully patented implantable neuro-stimulator to treat patients with moderate to severe obstructive sleep apnea (OSA). The therapy is indicated for patients who fail or who are intolerant to continuous positive airway pressure (CPAP) treatment.

The clinical evidence (published in the New England Journal of Medicine January, 2014) shows that Inspire therapy significantly reduces OSA severity, normalizes daytime functioning, reduces excessive daytime sleepiness, and significantly reduces snoring. Inspire's upper airway stimulation is unique in that it involves no anatomical alteration – it works with the patient's physiology, and unlike CPAP, it requires no facial apparatus.

It should also be noted that Inspire's implantable system is sold directly through Inspire-employed Territory Managers. There are no distributors involved in the sales process. Your Territory Manager is Jeff Smalley, and I know that Jeff is working with your hospital administration and your physician team to ensure that all the information and detail you require to approve this therapy is provided in a timely manner.

Thank you, and we look forward to working with you to provide Inspire therapy to those patients who will benefit from this exceptional technology.

Sincerely,



Tim Herbert
Inspire President and CEO

Attachment B

**SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS5000
Accepted until March 24, 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