Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin Agency Procurement Officer

Date: January 30, 2017

Re: Sole Source Certification Number **SS5075** for **PROTEKDuo System and associated accessories**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number SS5075 for PROTEKDuo System and associated accessories, please be advised that UMMC intends to award the purchase of the PROTEKDuo System and associated accessories to CardiacAssist Inc., dba Tandem Life as the sole source provider of the PROTEKDuo System and associated accessories.

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 30, 2017
Second Advertisement Date	February 6, 2017

Response Deadline from Objectors	February 13, 2017, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before March 20, 2017

Project Details

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

The University of Mississippi Medical Center, Department of Cardiology and Cardiac Surgery, is requesting to purchase products along with appropriate accessories associated with the PROTEKDuo system.

The PROTEKDuo system consists of a kit that contains a blood pump and a single lumen catheter. The PROTEKDuo catheter is a dual lumen catheter that is positioned in the main pulmonary artery and is used to support the right side of the heart during times of right heart failure. This technology provides a percutaneous option to further support our VAD and Heart Transplant programs without requiring the patient to undergo an invasive procedure in the Operating Room.

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

The PROTEKDuo system treats patient with Right Ventricular Failure post VAD placement or heart transplant without requiring a sternotomy. It is the only system that can be placed percutaneously with or without an oxygenator to support a failing right heart.

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

Tandem Life is the sole distributor for the PROTEKDuo System and associated accessories. See supporting letter from **CardiacAssist**, **Inc. dba Tandem Life**, 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 **PROTEKDuo System and associated accessories** is \$240K. 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 **PROTEKDuo System and associated accessories** (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 **CardiacAssist, Inc. dba Tandem Life**. 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 Monday, February 13, 2017, 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

Attachment A

TANDEM LIFE

Tuesday, November 22, 2016

Thomas Wills University of Mississippi Medical Center 2500 North State Street Jackson, MS 39216

Mr. Wills,

I am writing this vendor letter for your Sole Source Criteria.

TandemLife has the PROTEKDuo system. The PROTEKDuo kit contains a blood pump, which is regulated by the TandemHeart Escort Controller and a single dual lumen cannula. The single dual lumen cannula was designed to be inserted into the Right Internal Jugular with proximal holes positioned to drain the Right Atrium and distal holes to return blood from the blood pump to the Main Pulmonary Artery. This is the only system that can be used with or without an oxygenator percutaneously to support the failing right heart.

The PROTEKDUO system will help support patients with Right Ventricular Failure post durable VAD placement or post heart transplant without requiring a sternotomy to access the right atrium and Pulmonary artery for direct cannulation. The design for Right internal jugular access will not limit patient mobility while on support.

Lastly, our products are sold and shipped directly from our facility here in Pittsburgh. We do not use any distributors or re-sellers for distribution here in the USA.

Andy Bishop Director Customer Service and Materials CardiacAssist Inc. 240 Alpha Drive Pittsburgh, PA. 15238 412-963-7770 X 271 office 412-963-963-9739 fax

CardiacAssist, Inc. dba TandemLife | 240 Alpha Drive, Pittsburgh, PA 15238 | 412.963.7770 phone | 412.963.9739 fax

SUBMITTED IN RESPONSE TO Sole Source Certification No. SS5075 Accepted until February 13, 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