

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: March 23, 2017

Re: Sole Source Certification Number **SS5090** for **iTRACK Canaloplasty Microcatheter**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number SS5090 for iTRACK Canaloplasty Microcatheter, please be advised that UMMC intends to award the purchase of the iTRACK Canaloplasty Microcatheter to Ellex as the sole source provider of the iTRACK Canaloplasty Microcatheter.

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 23, 2017
Second Advertisement Date	March 30, 2017
Response Deadline from Objectors	April 6, 2017, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before May 4, 2017

Project Details

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

The University of Mississippi Medical Center Department of Ophthalmology is requesting continued purchase authority of the Ellex iTRACK Canaloplasty Microcatheter. The iTRACK is a specially designed microcatheter for use in patients with increased intraocular pressure related to open-angle glaucoma. This catheter is the only illuminable micron-scale microcatheter, via connection to the iLumen Fiberoptic Illuminator, which is currently in-house. This pairing allows the surgeon to successfully viscodilate Schlemm's canal.

The ability to perform minimally invasive trabeculectomy procedures by way of this microcatheter has shown a decrease in intraocular pressure as well as a decreased need for glaucoma medications in patients. Also, patients' visual acuity has improved following the procedure, all with very minimal complications. The decrease in pressure and decrease in medication dependency, as well as being able to see better, are great quality of life changes and increase patient satisfaction.

The Ellex iTRACK Microcatheter has the flexibility to enable a 360 degree cannulation of Schlemm's canal with a 250 micron bulbous atraumatic tip, designed to minimize potential for tissue damage, while an incorporated optical fiber allows transmission of light to the distal tip for continual transcleral surgical illumination and guidance. This catheter is the only 200 micron working-length diameter for minimally invasive procedures and it also contains a catheter support wire to maintain better control during catheterization of Schlemm's canal.

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

UMMC currently owns the iLumen Fiberoptic illuminator that the iTRACK catheter functions with. There are no other devices that will function with this equipment and provide the need for minimally invasive microcatheter procedures. The ability to provide minimally invasive microcatheter procedures will aid in our mission to improve health in our state as well as further education and training.

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

Ellex is the only vendor who offers the Ellex iTRACK Canaloplasty Microcatheter and the proprietary laser light source, iLumen Fiberoptic Illuminator. See supporting letter from Ellex, 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 iTRACK Canaloplasty Microcatheter is \$100,000. 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 iTRACK Canaloplasty Microcatheter (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 Ellex. 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, April 6, 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

Attachment A



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Minneapolis, MN USA 55344
ellex.com
☎ 1 952 881 9100 | 1 800 824 7444
☎ 1 952 941 5511

January 13, 2017

Re: Ellex iTrack 250™ Microcatheter and iLumin™ diode light source - Sole Source

Thank you for your expressed interest in the Ellex iTrack 250™ micro-catheter and iLumin diode light source for performing intraoperative Schlemm's Canal based surgery. Both systems are exclusive sole source, premium performance products manufactured, distributed and service by Ellex, Inc. in the US. These products have several unique features and benefits exclusively offered by Ellex.

The iTrack 250™ and iLumin provide the following benefits to your ophthalmologists, patients and center:

- The iTrack 250™ is manufactured as a 200 micron diameter single use flexible micro-catheter and a 250 micron distal tip which includes a red blinking light for visualization and precise maneuverability within Schlemm's Canal.
- The iLumin™ red diode light source accepts and proprietary connector from the iTrack 250™ catheter and is used to create the red blinking light that aids the surgical procedure.

These benefits provide your ophthalmologists and center with an exclusive surgical micro-catheter and light source that clearly offers exceptional patient treatment flexibility and outcomes.

Ellex is looking forward to working with you. If you have any questions please feel free to contact me at (843) 499-3180.

Sincerely,

A handwritten signature in black ink that reads "Mike Pickrel". The signature is fluid and cursive, with the first name "Mike" and last name "Pickrel" clearly distinguishable.

Mike Pickrel
Clinical Specialist

Attachment B

**SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS5090
Accepted until April 6, 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