

July 7, 2020

**Notice of Intent to Sole Source**  
**Multi-Axis Ultramicrotome Substrate Holder**  
**FDA\_SS\_1231773**

The Food and Drug Administration (FDA) intends to award a Sole Source firm-fixed price purchase order to Boeckeler Instruments, Inc, located at 4650 S. Butterfield Drive, Tucson, AZ 85714.

In accordance with FAR part 6.302-1, the contractor is the only responsible source who can provide the required services as no other source has been identified who can provide the requirements listed below.

The purpose of this notice is to inform the public that FDA anticipates issuing an award for the Multi-Axis Ultramicrotome Substrate Holder which is critical for assessing drug/device bioequivalence, in vitro cell and in vivo tissue toxicity to support science-based regulatory decision and to aid in collecting serial thin-sections and constructing 3D tomographic workflow with existing SEM and ultramicrotome.

**Multi-Axis Ultramicrotome Substrate Holder Specifications:**

1. Shall be compatible with an existing Leica EM UC7 ultramicrotome system.
2. Shall be assembled to the Leica EM UC7 by simply clamping.
3. Shall be used with standard room temperature DiATOME diamond knives or jumbo diamond knives.
4. Shall be able to clamp a 25 mm square substrate.
5. Shall be able to precisely align the substrate by moving at x, y, and z directions.
6. Shall come equipped with a water drain system that can drive thin sections onto the substrates.
7. Shall have the ability to collect serial sections (minimum hundreds of thin sections) to allow for 3D image re-construction of objects of interest.

The associated North American Industrial Classification System (NAICS) Code is 334519: Other Measuring and Controlling Device Manufacturing.

***This notice is not a request for competitive proposals.*** However, any party that believes it is capable of meeting this requirement as stated herein may submit a written capability statement that clearly supports and demonstrates their ability to perform the requirement.

Capability statements must be received by the response date and time of this notice. Submissions will be reviewed to determine if they can meet the requirement. A determination by the Government to compete this proposed contract based upon responses to this notice is solely within the discretion of the Government.

It is anticipated that an award will be issued to Boeckeler Instruments, Inc, within approximately ten (10) days after the date of this notice unless the Government determines that any other organization has the capability to meet this requirement.

**Response Date: July 17, 2020 by 10:00AM Eastern Standard Time.** Please email responses to Nicole Craig at [nicole.craig@fda.hhs.gov](mailto:nicole.craig@fda.hhs.gov). No phone calls will be accepted.