

JUSTIFICATION FOR SINGLE SOURCE AWARDS IAW FAR 13.106-1
(OVER MICRO-PURCHASE THRESHOLD(\$3K) BUT NOT EXCEEDING THE SAT (\$150K))

IAW [FAR13.104](#), COs must promote competition to the maximum extent practicable to obtain supplies and services from the source whose offer is the most advantageous to the Government, considering the administrative cost of the purchase. When competition is not practicable, IAW [FAR13.106-1\(b\)](#), COs solicit from a single source for purchases not exceeding the simplified acquisition threshold. COs may solicit from one source if the CO determines that the circumstances of the contract action deem only one source reasonably available (e.g., urgency, exclusive licensing agreements, brand-name or industrial mobilization). IAW [FAR13.106-3\(b\)\(3\)](#), COs are required to include additional statements ***explaining the absence of competition*** (see [13.106-1](#) for brand name purchases) if only one source is solicited and the acquisition does not exceed the simplified acquisition threshold (does not apply to an acquisition of utility services available from only one source) or supporting the award decision if other than price-related factors were considered in selecting the supplier. This template when completed can be used to document single source awards IAW [FAR13.106-3\(b\)\(3\)](#). Note: Statements such as "only known source" or "only source which can meet the required delivery date" are inadequate to support a sole source purchase.

1. PURCHASE REQUEST OR REQUISITION NUMBER:

541-15-4-2521-0514 C-Fine
541-15-4-2521-0539 Electrode Cuffs

**1A. PROJECT/TASK
NUMBER**

213

1B. ESTIMATED AMOUNT:

\$17231.36

2. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES REQUIRED AND THE INTENDED USE:

The Department of Veterans Affairs, Cleveland Medical Center (VAMC), Advanced Platform Technology (APT) Center of Excellence, has a requirement for Custom 5-pole nerve cuff electrodes with inter-electrode spacing of 4mm and 35mm 'flying leads':

3 @ 2mm diameter
3 @ 2.5mm diameter
3 @ 3mm diameter

And next generation nerve cuff electrodes (cFines). Per FDA requirements, the new cuff must pass pyrogenicity testing, which will be performed by an outside vendor that is certified in conducting these tests. This purchase is for the cFines (test articles) to be used in the pyrogenicity tests. This contract covers the cost of materials and labor to develop the cFINE test articles. Specifically 2 lots of 3 cFines (a total of 6 cFines) will be manufactured.

What the cuff does: These nerve cuff electrodes are used to deliver controlled stimulation to a nerve in order to restore one or more functions, typically lost due to spinal cord injury or stroke. These cuffs also provide the ability to restore sensation that is lost following amputation.

3. UNIQUE CHARACTERISTICS THAT LIMIT AVAILABILITY TO ONLY ONE SOURCE, WITH THE REASON NO OTHER SUPPLIES OR SERVICES CAN BE USED:

These electrodes need to be custom made with the specific electrode spacing and lead length required for our studies. The electrode spacing is based on computer simulations and maximizes the ability to selectively stimulate different sections of the nerve that are responsible for different functions and/or sensations. The manufacturer chosen (Ardiem Medical) is the only manufacturer licensed to fabricate these cuffs. Due to the nature of the customizable nature of the cuffs (cuff length and width, number of stimulating channels, inter-channel distance), the cuffs are only manufactured on a custom, by-request basis.

Unique characteristics: The cuffs are made of human-grade, unrestricted, implantable silicone. The electrodes within the cuff need to be customized with the specific electrode spacing and lead length required for our studies. The electrode spacing is based on computer simulations and maximizes the ability to selectively stimulate different sections of the nerve that are responsible for different functions and/or sensations. The manufacturer chosen (Ardiem Medical) is the only manufacturer licensed to fabricate these cuffs. Due to the customizable characteristics of the cuffs (cuff length and width, number and distribution of stimulating electrodes), the cuffs are only manufactured on a custom, by-request basis.

4. REASON THAT SUGGESTED SOURCE IS THE ONLY SOURCE, WHICH CAN PROVIDE THE SUPPLIES OR SERVICES:

The cuff is approved under an FDA Investigational Device Exemption (IDE) and deviations outside of the specifications in the Design Master File (DMF) are not permitted. Therefore, very precise controls must be in place to assure accurate and safe manufacture of the device. This includes not only the materials used in the device, but the manufacturing facility and process. Ardiem is the only manufacturer we have found capable of producing custom, implantable, human-grade devices in small quantities under these strict controls.

5. DESCRIPTION OF MARKET RESEARCH CONDUCTED AND RESULTS OR STATEMENT WHY IT WAS NOT CONDUCTED:

The engineers at the Cleveland VAs Advanced Platform Technology Center regularly assesses the available electrodes on the market by attending a range of annual conferences in which all major electrode vendor display their products. They also assess researcher needs and then works to fill in the gaps by making electrodes themselves and then transferring their manufacturing techniques to vendors such as Ardiem to continue to supply the various types of electrodes required by the research community.

6. Contracting Officer's Certification: *Purchase is approved in accordance with FAR13.106-1(b). I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.*

Signature: _____

Date: _____

Name: _____

Title: _____

Facility: _____