JUSTIFICATION AND APPROVAL
FOR OTHER THAN FULL AND OPEN COMPETITION

1. Contracting Activity: Department of Veterans Affairs (VA)
Office of Acquisition Operations
Strategic Acquisition Center (SAC)
10300 Spotsylvania Avenue, Suite 400
Fredericksburg, VA 22408

2. Description of Action: The action being approved is for a modification to the Indefinite Delivery Indefinite Quantity (IDIQ) to continue the supply of Cardiac Implants under the contracts identified in Table 1 by extending the ordering period by (60) days. The extension of the ordering periods will be henceforth referred to as "bridge modifications." These bridge modifications will affect the following Multiple Single Award Cardiac Implant IDIQ contracts awarded to the following vendors and respective period of performance:

Table 1: Current VA CardioVendors on National Contracts

Vendor	Contract Number	Original Period of Performance	Proposed Period	Estimated Value
Biotronik, Inc.	V797-P-0216	9/15/2011-9/14/2016	9/15/2016-11/10/2016	
St. Jude	V797-P-0277	9/15/2011-9/14/2016	9/15/2016-11/10/2016	
Medtronic	V797-P-0218	10/01/2011-9/30/2016	9/30/1206-11/30/2016	
Boston Scientific	V797-P-0217	9/15/2011-9/14/2016	9/15/2016-11/10/2016	

The combined estimated value of the proposed actions is

The purpose behind this justification and approval (J&A) is to provide bridge modifications for the aforementioned contracts. These contracts were identified as part of the Top 20 vendors supplying implants of varying types to the VA. The VA has statutory authority to utilize other than full and competitive acquisition procedures. (See paragraph 4 below). This proposed bridge extension consist of a sixty days period of performance and will prevent a diverse impact on the enhancement of medical care provided to our Veterans, which would occur with the interruption of the implants presently provided under each contract.

3. Description of Supplies or Services:
The product descriptions under the bridge modifications remain the same as under the current contracts. The Veterans Health Administration (VHA) Prosthetics and Sensory Aids Services (PSAS) have a need for Cardiac Implants (Cardiac Resynchronization Therapy Devices). A physician's decision to use a particular manufacture's implant is based on "physician determination of medical necessity/experience". Using a particular manufacturer's implants requires

highly specialized training on the part of the physician. Once trained and comfortable with a particular manufacturer's implants, the physician will likely use that manufacturer's product for the duration of their career. In addition, instrumentation sets and auxiliary products are distributed by the manufacturer since they are an essential part of the "procedural package" and required at the time of surgery. This provides the physician with all necessary implant appliances needed to complete the surgery. The Table below identifies the types of Cardiac Implants being procured by the VA for its veterans.

Table 2: Cardiac Resynchronization Therapy Devices

Cardiac Resynchronization Therapy Devices(Pacing)-CRT-P
Cardiac Resynchronization Therapy Devices (with Defibrillation)
Transvenous high voltage leads
Low Voltage steroids-eluting
Left ventricular(coronary sinus) lead
Left ventricular(coronary sinus) lead delivery system

Currently, there are approximately 8,952 Cardiac Implants of many different types implanted into or onto the veterans each year. Cardiac Implants are obtained through a decentralized ordering process and are surgically implanted by surgeons employed by VA Medical Centers throughout the United States and its territories.

The request for follow-on contracts was submitted through an email on 22 August 2016 by VHA Prosthetic Sensory Aid Service (PSAS).

4. Statutory Authority: The statutory authority permitting other than full and open competition is 38 U.S.C. Section 8123 and 41 U.S.C. 253(c)(5) and implemented by the FAR 6.302-5(a)(2)(i) and VAAR 806.302-5(b)(1), Authorized by Statute.

5. Rationale Supporting Use of Authority Cited Above: The continuity of supply of Cardio Implant (Cardiac Resynchronization Therapy Devices) for all contracts listed in Table 1 is required. The multiple vendors allow clinician and surgeons the latitude to select implant based upon specific patient needs or by "prescription." The government is able to maximize efficiency of use of the latest available implants in the commercial market place. A single vendor is not able to meet all of the government's needs therefore the award group is considered to be a responsible

source when capabilities are combined. In addition, the current group of vendors is the only known manufacturers of the product in the U.S.; full and open competition through another contracting vehicle would not render a different result or provide a better business arrangement for the government. These same vendors are also being sought for follow on sole source contracts after the expiration of proposed period. These bridge modifications will provide the necessary time to award new contracts. In addition, for the sixty days period it would be impractical to seek a new vendor to include resellers if any were deemed capable for such a short time-frame. The contractor would be required to demonstrate technical capability through a written proposal or quote and provide a fair and reasonable price to the government. The technical and price proposal or quote would have to be evaluated for acceptance. Furthermore, there is not enough time to complete the required actions if it was feasible. The contractor would also be required to establish the proper infrastructure and manpower to be able to provide the required product for the sixty days period. The foregoing is not a viable option. Therefore, Multiple Single Award sixty days bridge modifications, extending ordering period for contracts listed in Table1 above is required. These modifications will provide the continuity of products and services in support of veterans with disabilities while at the same time provide for a seamless transition to the anticipated follow on contracts.

6. Efforts to Obtain Competition: Formal market research was conducted, details of which are in the market research section of this document. (See paragraph 8 below). Competitive offers were not sought for the proposed period. Vendors listed in Table 1 above are the incumbent contractors and are considered to be amongst the TOP 20 vendors the VA has identified for sole source contracts and are uniquely qualified to provide the required implants. This J&A will be synopsized on the Federal Business Opportunities Page in accordance with FAR 5.201.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable: Vendors have agreed to honor sixty 60 days price for the proposed sixty days periods. The base year and option years pricing were determined fair and reasonable at the time of award through effective price competition, according to the FAR is the most effective means to determine fair and reasonableness. In addition, prices were determined to be reasonable by the procuring contracting officer through an independent price analysis. Therefore, the anticipated cost of the proposed bridge modifications are considered fair and reasonable based on historical pricing or previous prices paid for the same items.

8. Market Research: Market research was conducted prior to awarding cardio contracts; there were four (4) vendors, all manufacturers that proposed and all vendors were awarded multiple single award IDIQ contracts. Market research conducted for the follow on requirement revealed that the same vendors are interested and capable of providing the required implants. The approval of this J&A will allow the VA to be able to issue delivery orders for an additional sixty days for previously competed contracts. The Government will continue to conduct market research to ascertain if there are changes in the market place that would ensure further competition for future actions.

This Justification and Approval document will be posted within 14 days after a contract modification has been issued in accordance with FAR 6.305.

9. Other Facts: None

10. A list of the sources, if any, that expressed, in writing, and Interest in the acquisition: None at this time.

11. Technical and Requirements Certification: I certify that the supporting data under my cognizance, which are included in this justification, are accurate and complete to the best of my knowledge and belief.

Name: for Penny Nechanicky

Date: 9-13-16

Title: National Director
Prosthetics Sensory Aides Service

Signature:

12. Contracting Officer Determination: I certify that this justification is accurate and complete to the best of my knowledge and belief. I hereby determine that the anticipated price to the Government for this contract action will be fair and reasonable based on *historical prices paid for these services.*

Name: Lori A. Smith

Date: Smith, Lori

Title: Contracting Officer

Signature: Lori

Digitally signed by Smith, Lori
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Approval

In my role as Procurement Activity Competition Advocate, based on the foregoing justification, I hereby approve the modification of Cardio Implants Contract Nos. V797-P-0216; V797-P-0277; V797-P-0218; V797-P-0217 on an other than full and open competition basis pursuant to the statutory authority 38 U.S.C. Section 8123 and 41 U.S.C. 253(c)(5) and provided that the property and services herein described have otherwise been authorized for acquisition.

Date: _____ Signature: Primus, Elegear

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Date: 2016.09.14 16:51:14 -04'00'

Elegear J. Primus
Deputy Associate Executive Director