

DEPARTMENT OF VETERANS AFFAIRS

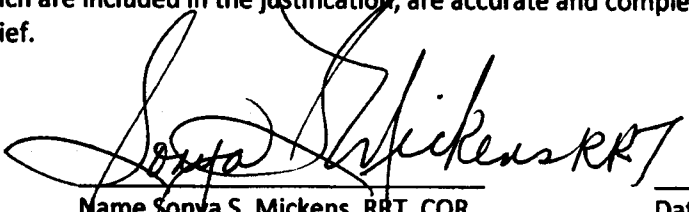
Justification and Approval

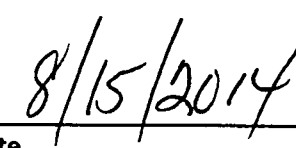
For

Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, VISN 08 Bay Pines VA Medical Center Medicine Service Dept. is requesting replacement temporary pacemaker generators for manufacturer recalled pacemaker generators out of warranty in cardiac cath lab and ICUs. Medtronic has quoted these replacement pacemaker generators with a turn allowance for these recalled units.
2. **Nature and/or Description of the Action Being Processed:** Replacement of pacemaker generators is recommended and approved for purchase.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Four (4) temporary pacemaker generators, model 5392, to be purchased at a total purchase price of [REDACTED] with a trade in rebate of [REDACTED]. These units will replace recalled units already in place in the Bay Pines cardiology/ICU sections.
4. **Statutory Authority Permitting Other than Full and Open Competition:**
 - (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
 - () (2) Unusual and Compelling Urgency per FAR 6.302-2;
 - () (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
 - () (4) International Agreement per FAR 6.302-4
 - () (5) Authorized or Required by Statute FAR 6.302-5;
 - () (6) National Security per FAR 6.302-6;
 - () (7) Public Interest per FAR 6.302-7;
5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** This is an emergency request to replace units recalled due to safety issues. The manufacturer will provide trade in rebates for current units in place. A subset of Model 5388 Dual-Chamber External Temporary Pulse Generators worldwide may be unable to power up or may power down unexpectedly. The issue presents itself in one of two ways. First, during startup, and prior to initiating patient therapy, the instrument may power down in 1 - 2 seconds. Second, the instrument may power up correctly, but power down at a later time while in use.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** SEE ABOVE
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The cost quoted has been similar to the previous purchases of the same equipment.

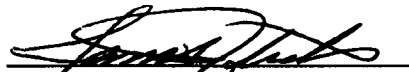
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Initial market research reveals the requested items are available via the recommended vendor of the requested product. A search of FSS, GSA and NAC revealed no current contracts for the requested item. This item is considered a Cardiopulmonary Diagnostics Department. The NACIS code is 339113 and the FSC is 6515. The items being request can only be provided by the vendor MEDTRONIC USA, Inc since there is a manufacture recall of the Pacemaker which is out of warranty; the manufacturer will provide trade in/discount rebates for current units in place. There are no other distributors of these products
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** Medtronic issued an Important Medical Device Correction letters to hospital's biomedical engineering department. The letter described the issue, how it presents, and stated that Medtronic will contact the hospitals to return affected product for servicing. The second letter reiterated that Medtronic would notify customers when FDA approves their design upgrade for returning devices for service. In the interim, hospitals should continue to use normally functioning devices.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** MEDTRONICS
11. **A Statement of the Actions, if any, the Agency May Take to Remove or overcome any Barriers to Competition before making subsequent acquisitions for the supplies or services required:** The items to be purchased are direct replacements for recalled items.
12. **Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.



Name Sonya S. Mickens, RRT, COR
Title: Chief, Cardiopulmonary Diagnostics and Therapeutic Section
Facility: Bay Pines VAHCS


Date 8/15/2014

13. **Approvals in accordance with FAR 6.304**

- a. **Contracting Officer's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.


Name: James Roberts
Title: Contracting Officer
Facility: Bay Pines VAHCS


Date 8-25-14

- b. **Product Line Supervisor \$3K and above):** I certify the justification meets requirements for other than full and open competition.



Name: **BRIAN K. MACLEAN**
VISN 8 **SUPERVISORY CONTRACT SPECIALIST**

Title Product Line Supervisor
Facility Bay Pines

8/25/14
Date

- c. **SAO (If over 650K):** I certify the justification meets requirements for other than full and open competition.

Name: Eldred Jackson
Acting Director
Service Area Office, East

Date

- d. **VHA HCA Review and Approval:** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and recommend approval (if over \$12.5 million) or approve (\$650K to 12.5 million) for other than full and open competition.

Name
Chief Procurement and Logistics Officer
VHA Head of Contracting Activity (HCA)

Date

- e. **VA Deputy Senior Procurement Executive Approval (over \$12.5 million but not exceeding \$50 million):** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

C. FORD HEARD
Deputy Senior Procurement Executive (DSPE)
Office of Acquisition and Logistics
Department of Veterans Affairs

Date

- f. **VHA Senior Procurement Executive Approval (over \$50 million):** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

Jan R. Frye
Deputy Assistant Secretary for Acquisition and Logistics
Senior Procurement Executive (SPE)
Department of Veterans Affairs

Date