

JUSTIFICATION FOR OTHER THAN FULL AND OPEN COMPETITION

IN ACCORDANCE WITH FAR 6.303-2 – CONTENT

REMOTE MONITORING SYSTEM

(1) Agency & Contracting Activity:

Department of Veterans Affairs
National Acquisition Center
Hines, IL 60141

(2) Action:

Sole Source Justification to contract with Biotronik for a requirements type contract with one (1) year base period and four (4) one (1) year option periods.

The VA National Cardiac Device Surveillance Center (VANCDSC) was established as a national special program by the Patient Care Service in 2003 to provide remote monitoring of implanted cardiac devices (ICD, pacemakers and CRT) with such functionality.

(3) Item Description:

Biotronik Home Monitoring System, an internet and telephone based service, using remote monitoring equipment that provides the capability for Clinicians to monitor the Patient's cardiac device and gather related data similar to what is required in an office visit.

Product	Catalog Number
Bradycardia	
<u>Dual-Chamber Pacing Systems (with Home Monitoring)</u>	
Evia DR-T dual-chamber pacing system with Home Monitoring	377846
Cylos DR-T dual-chamber pacing system with Home Monitoring	360754
Philos II DR-T dual-chamber pacing system with Home Monitoring	360755
<u>Dual-Chamber Pacing Systems (with Home Monitoring Mobile)</u>	
Evia DR-T dual-chamber pacing system with Home Monitoring Mobile	377847
Cylos DR-T dual-chamber pacing system with Home Monitoring Mobile	356057
Philos II DR-T dual-chamber pacing system with Home Monitoring Mobile	348447
<u>Dual-Chamber Pacemakers (with Home Monitoring)</u>	
Evia DR-T pacemaker with Home Monitoring	359529
Cylos DR-T pacemaker with Home Monitoring	349806
Philos II DR-T dual-chamber pacemaker with Home Monitoring	343175

<u>Dual-Chamber Pacemakers (with Home Monitoring Mobile)</u>	
Evia DR-T pacemaker with Home Monitoring Mobile	377848
Cylos DR-T pacemaker with Home Monitoring Mobile	356808
Philos II DR-T dual-chamber pacemaker with Home Monitoring Mobile	351839

<u>Single-Chamber Pacing Systems (with Home Monitoring)</u>	
Evia SR-T dual-chamber pacing system with Home Monitoring	377849

<u>Single-Chamber Pacing Systems (with Home Monitoring Mobile)</u>	
Evia SR-T dual-chamber pacing system with Home Monitoring Mobile	377850

<u>Single-Chamber Pacemakers (with Home Monitoring)</u>	
Evia SR-T pacemaker with Home Monitoring	359533

<u>Single-Chamber Pacemakers (with Home Monitoring Mobile)</u>	
Evia SR-T pacemaker with Home Monitoring Mobile	377851

Tachycardia

<u>Dual-Chamber ICD Systems (with Home Monitoring)</u>	
Lumax 540 DR-T dual-chamber ICD system with Home Monitoring	362726
Lumax 340 DR-T dual-chamber ICD system with Home Monitoring	359656

<u>Dual-Chamber ICD Systems (with Home Monitoring Mobile)</u>	
Lumax 540 DR-T dual-chamber ICD system with Home Monitoring Mobile	368771
Lumax 340 DR-T dual-chamber ICD system with Home Monitoring Mobile	359655

<u>Dual-Chamber ICDs (with Home Monitoring)</u>	
Lumax 540 DR-T dual-chamber ICD with Home Monitoring	360346
Lumax 340 DR-T dual-chamber ICD with Home Monitoring	355267

<u>Dual-Chamber ICDs (with Home Monitoring Mobile)</u>	
Lumax 540 DR-T dual-chamber ICD with Home Monitoring Mobile	368769
Lumax 340 DR-T dual-chamber ICD with Home Monitoring Mobile	359654

<u>Single-Chamber ICD Systems (with Home Monitoring)</u>	
Lumax 540 VR-T single-chamber ICD system with Home Monitoring	362724
Lumax 340 VR-T single-chamber ICD system with Home Monitoring	359666

<u>Single-Chamber ICD Systems (with Home Monitoring Mobile)</u>	
Lumax 540 VR-T single-chamber ICD system with Home Monitoring Mobile	368775

Lumax 340 VR-T single-chamber ICD system with Home Monitoring Mobile	359665
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Single-Chamber ICDs (with Home Monitoring)

Lumax 540 VR-T single-chamber ICD with Home Monitoring	360348
Lumax 340 VR-T single-chamber ICD with Home Monitoring	355271

Single-Chamber ICDs (with Home Monitoring Mobile)

Lumax 540 VR-T single-chamber ICD with Home Monitoring Mobile	368776
Lumax 340 VR-T single-chamber ICD with Home Monitoring Mobile	359664

Cardiac Resynchronization Therapy (CRT)

CRT-D Systems (with Home Monitoring)

Lumax 540 HF-T System with Home Monitoring with ScoutPro	362725
Lumax 540 HF-T System with Home Monitoring without ScoutPro	367843
Lumax 340 HF-T System with Home Monitoring with ScoutPro	359662
Lumax 340 HF-T System with Home Monitoring without ScoutPro	359661
Lumax 340 HF-T System with Home Monitoring without CS Lead	359663

CRT-D Systems (with Home Monitoring Mobile)

Lumax 540 HF-T System with Home Monitoring Mobile with ScoutPro	368773
Lumax 540 HF-T System with Home Monitoring Mobile without ScoutPro	368774
Lumax 340 HF-T System with Home Monitoring Mobile with ScoutPro	359659
Lumax 340 HF-T System with Home Monitoring Mobile without ScoutPro	359658
Lumax 340 HF-T System with Home Monitoring Mobile without CS Lead	359660

CRT-D Devices (with Home Monitoring)

Lumax 540 HF-T with Home Monitoring	360347
Lumax 340 HF-T with Home Monitoring	355263

CRT-D Devices (with Home Monitoring Mobile)

Lumax 540 HF-T with Home Monitoring Mobile	368772
Lumax 340 HF-T with Home Monitoring Mobile	359657

(4) Statutory Authority:

41 U.S.C. 253(c) authorizes, under certain conditions, contracting without providing for full and open competition. Only one responsible source and no other supplies or services will satisfy the agency's requirements.

(5) Unique Qualifications:

The Prosthetics Sensory Aids Service (PSAS) has determined that the need for the remote monitoring system from Biotronik and is required for the following reasons:

- Remote monitoring allows close follow-up of device function without clinic visits. At present, devices from about 15,000 veterans are being remotely monitored by VANCDSC. Each device vendor (manufacturer) has its own proprietary technology for communication with its devices and remote transmission of the interrogated data. Accordingly, a separate contract with Biotronik is required for remote monitoring of its own devices.

(6) Publication of Sources Sought:

A Sources Sought – Notice of Intent to Negotiate a Sole Source contract was published in Federal Business Opportunities (FedBizOpps) website (numbered VA-797-11-RP-0001, dated 10/21/2011). One vendor Guardian Cardiac Device Monitoring, LLC., responded to the sources sought notice. After speaking with a representative from Guardian it was determined they could not provide remote monitoring of implanted Biotronik devices.

(7) Fair & Reasonable Pricing:

No Cost Procurement.

(8) Market Research:

Market Research was conducted and determined that no vendors offer a universal remote monitoring system that could monitor any manufacturer's device.

(9) Other Facts Supporting "Other Than Full and Open Competition":

PSAS's defibrillators (ICD), pacemakers and cardiac resynchronous therapy devices (CRT) Integrated Product Team (IPT) is made up of clinical experts in the field of cardiac care. The members of the group work directly with patients in prescribing these devices and are aware of the products offered in the commercial market place. It is the user group's medical determination that no other company can offer the medical advantages for VA patients of the Biotronik specific remote monitoring devices that are being sought under this sole source procurement.

(10) Other Sources:

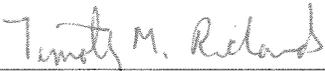
While there are other remote monitoring devices in the commercial market place, no other remote monitoring system possess the unique and patented features of the Biotronik monitoring device which will be used solely to monitor Biotronik manufactured cardiac implants.

(11) Actions to Overcome Barriers to Full & Open Competition in Future Procurements:

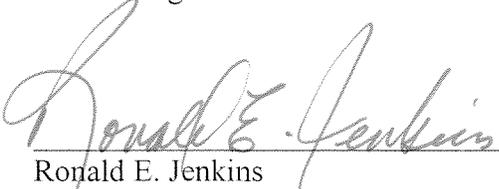
Future technology may offer opportunities for companies to develop universal remote monitoring devices and thus, increase competition. Plus, all future procurements will continue to be advertised in the Federal Business Opportunities website for the purpose of obtaining competition.

(12) Certification:

I hereby certify that the foregoing justification and the supporting data (signed certification) for other than full and open competition is accurate and complete to the best of my knowledge and belief.



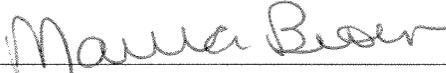
Timothy M. Richards Date
Contracting Officer



Ronald E. Jenkins Date
Assistant Director, National Contract Service

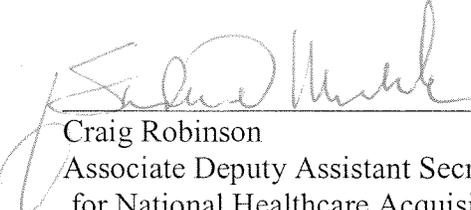


Steven A. Thomas Date
Director of National Contracts Service



Maura Brown Date
Attorney
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Approve () Do Not Approve ()



Craig Robinson Date
Associate Deputy Assistant Secretary
for National Healthcare Acquisitions
Department of Veterans Affairs
National Acquisition & Logistic Center