

Summary of P010015 / S227 (180-Day PMA Supplement and Amendment 001)
Bundled File with P890003 / S297, P010031 / S414, P980016 / S452 and P980035 / S358
Medtronic – Viva CRT-P and Modifications to Supporting External Devices

PURPOSE OF SUBMISSION

The Medtronic Viva CRT-P Model C6TR01 cardiac resynchronization therapy implantable pulse generator (CRT-P) device consists of the Consulta CRT-P device model C4TR01 (P010015/S084, March 22, 2011) with the addition of the following features:

- AdaptivCRT algorithm (AdaptivCRT)
- CardioSync Optimization Test
- On-screen Cardiac Compass
- On-screen rate histograms and percent CRT pacing (Bi-V and LV)

The features listed above were approved as part of the Viva XT CRT-D device (P010031/S318, January 29, 2013). The addition of these features to the Consulta CRT-P platform has been discussed with FDA via pre-IDE Q130884, with primary focus on the Adaptive CRT algorithm and the clinical data supporting its safety and efficacy. Per agreement with FDA, Medtronic is referencing data from the Adaptive CRT clinical report to support approval of the AdaptivCRT algorithm in the Viva CRT-P device.

The Viva CRT-P device is a multi-programmable, cardiac resynchronization therapy implantable pulse generator. It provides biventricular pacing for cardiac resynchronization therapy and monitors and regulates a patient’s heart rate by providing dual chamber rate-responsive bradycardia pacing, diagnostics and atrial therapies.

The AdaptivCRT is designed to provide patient-specific selection of the pacing configuration (left-ventricular only or bi-ventricular pacing) as well as device atrio-ventricular (AV) and interventricular (VV) delays and dynamic adjustment of these parameters based on periodic automatic evaluation of intrinsic electrical conduction intervals.

This PMA Supplement provides supporting information and data that substantiates safety and effectiveness of the Viva CRT-P device and requests approval for the implantable device, CareLink Programmer application software, firmware (FW) upgrades for the CareLink instruments to recognize the implantable devices and CareLink Network Device Data Management Application (DDMA) upgrades to support the device features as identified in **Table 3-1**. In addition, **Table 3-1** also identifies the compatible commercially available system components and instruments that will be used with the Viva CRT-P device.

Table 3.1

Original PMA	P010015	P890003	Compatible Commercially Available System Components
Viva CRT-P	<p>Master File</p> <p>Subject of this PMA-S</p> <ul style="list-style-type: none"> • Viva CRT-P C6TR01 • Programmer Application Software (SW9995 v8.3) 	<p>CareLink Instruments & DDMA</p> <p>Refer to File letter</p> <p>Subject of this PMA-S</p> <ul style="list-style-type: none"> • CareLink Home Monitor (2490G) FW upgrade only • CardioSight Reader (2020A) FW upgrade only • CareLink Express Monitor Model (2020B) FW upgrade only • CareLink Network Device Data Management Application (2491) upgrades to support implantable device features 	<ul style="list-style-type: none"> • Pacing leads • CareLink Programmer (2090) • CareLink Encore Programmer 29901 • Analyzer (2290) • InCheck Patient Assistant (2696) • Smart Magnet (9322) • Patient Magnet (9466) • Implant support instruments and accessories

Overview of Changes

The Viva CRT-P device model C6TR01 is based on the Consulta CRT-P device model C4TR01. An overview of the Viva CRT-P system changes are shown in the following table(s)

Added Features	Change / Reason for Change
<p>AdaptivCRT Algorithm Provides automatic adjustment of CRT settings (PAV, SAV, and V-V delays and the ventricular pacing configuration) based on periodic measurements of the patient's intrinsic AV conduction durations and P-wave and QRS complex widths.</p>	<p>The underlying AdaptivCRT algorithm remains unchanged between the algorithm used in the Adaptive CRT Clinical Study, the Viva XT CRT-D and the Viva CRT-P device implementations. The following are the differences to incorporate the feature approved for Viva XT CRT-D into the Viva CRT-P product:</p> <ul style="list-style-type: none"> • Firmware implementation – Where the AdaptivCRT algorithm was in (b)(4)T code for Viva XT CRT-D, it is installed in device (b)(4) IS/CCI or Viva CRT-P and will be reinstalled automatically on programmer interrogation of the device in the unlikely event it is lost on a device reset. This implementation eliminates the need to maintain (b)(4) TS/CCI manufacturing. • Far-field electrogram waveform measurement vector adjustment – Where the Viva XT CRT-D device could adjust the far-field electrogram vector between 'Can to Aring' and 'Can to SVC' during AdaptivCRT's 16-hour waveform width measurements based on the most recent SVC lead impedance measurement results, the Viva CRT-P device does not have the Can to SVC EGM vector. The Viva CRT-P device uses 'Can to Aring' vector for width measurements provided the most recent Atrial bipolar lead impedance is in range. Otherwise, default waveform width values are used. • Automatic Implant detection integration – Where the Viva XT CRT-D device implant detection is satisfied by programming VF detection On (which starts a 30-minute timer to AdaptivCRT's first measurements), the Viva CRT-P device uses Automatic Implant detection (or manual programming of implant detection) to determine whether implant has occurred and initiate the 30- minute timer to AdaptivCRT's first measurements. • LV pace-“fibrillation” sense sequence operation – Where the Viva XT CRT-D device forces Adaptive Bi-V operation for 3 minutes when 3 LV pace-fibrillation sense event sequences indicate VF episode onset, the Viva CRT-P device does identify fast ventricular events as fibrillation sensed events. To emulate the ICD operation in a CRT IPG, the Viva CRT-P device will force Adaptive Bi-V operation for 3 minutes when the device identifies consecutive LV pace-ventricular sense intervals less than 320 ms.
<p>CardioSync Optimization Test Provides in-office CRT pacing configuration settings based on the AdaptivCRT feature.</p>	<p>The underlying CardioSync Optimization Test remains unchanged from the Viva XT CRT-D implementation. The following is the differences to incorporate the feature approved for Viva XT CRT-D into the Viva CRT-P product:</p> <ul style="list-style-type: none"> • Far-field electrogram waveform measurement vector adjustment – Where the Viva XT CRT-D device could adjust the far-field electrogram vector between 'Can to Aring' and 'Can to SVC' during the CardioSync Optimization Test measurements based on the most recent SVC lead impedance measurement results, the Viva CRT-P device does not have the Can to SVC EGM vector. The Viva CRT-P device uses 'Can to Aring' vector for the test width measurements provided the most recent Atrial bipolar lead impedance is in range. Otherwise, default waveform width values are used.
<p>On-Screen Cardiac Compass Session Management – Provides Cardiac Compass diagnostics and Rate Histograms diagnostics for on screen display via the programmer</p>	<p>No changes</p>
<p>On-Screen Rate Histograms & Percent CRT Pacing (Bi-V and LV) Session Management – Provides Cardiac Compass diagnostics and Rate Histograms diagnostics for on screen display via the programmer</p>	<p>No changes</p>

Modified Feature	Devices Impacted	Description / Rationale
Atrial Tracking Recovery	Viva CRT-P	Modified to change the shipped and nominal settings from Off to On. Loss of atrial tracking can reduce the benefits of CRT pacing. Long A-VP intervals can result in intrinsic p-waves falling within PVARP, causing asynchronous ventricular pacing. The Atrial Tracking Recovery (ATR) feature recognizes that pattern and restores atrial tracking. ATR is a market-released feature that is available in Medtronic market released devices.
TherapyGuide	Viva CRT-P	Modified to provide recommendations for AdaptiveCRT feature programming.
Automatic Implant detection / Mode Switch	Viva CRT-P	Correction of Mode Switch feature interaction with IPG Implant Detection operation.
Automatic Implant detection /Pacing Polarity (LV)	Viva CRT-P	Prevention of IPG Implant Detection scenario where LV pacing polarity programming is delayed.
EGM Real-time and Stored Channels	Viva CRT-P	Correction of EGM and marker data misalignment scenario
Longevity Estimator	Viva CRT-P	Correction to address scenario where battery measurements are not taken.
Atrial Capture Management/POR Operation	Viva CRT-P	Prevention of parameter programming inconsistency following a device reset
Patient Activated Episode Storage	Viva CRT-P	Removal of EGM reference strip recording functionality to prevent pauses during ventricular pacing
Automatic Implant Detection	Viva CRT-P, Consulta CRTP, Syncra CRT-P, Advisa DR, Ensura DR	Display of Implant Detection not complete notification
Automatic Implant Detection / Sensing Polarity	Viva CRT-P, Consulta CRTP, Syncra CRT-P, Advisa DR, Ensura DR	Prevention of a scenario on manual programming of automatic implant detection where an undesired sensing polarity configuration could be simultaneously selected.
Patient Diagnostics/Monitoring	Viva CRT-P, Consulta CRTP, Syncra CRT-P, Advisa DR, Consulta CRT-D, Concerto II CRT-D, Maximo II CRT-D, Secura DR, Virtuoso DR, Maximo II DR, Secura VR, Virtuoso II VR, Maximo II VR	Display of data corrected via Cyclic Redundancy Check
Cardiac Compass Trends	Viva CRT-P, Consulta CRTP, Advisa DR, Consulta CRT-D, Concerto II CRT-D, Secura DR, Virtuoso II DR, Secura VR, Virtuoso VR	Correction of clipped session annotation

Other Changes	Devices Impacted	Description / Rationale
Hardware Shield Graphics	Viva CRT-P	New brand name and device model
Firmware	Viva CRT-P	Base firmware is identical to Consulta CRT-P; RAMware additions incorporate the new feature functionality
Software	Viva CRT-P	Modified to XMLTU to support AdaptivCRT settings and Percent CRT Pacing (BiV and LV) histograms
Manuals & Labels	Viva CRT-P	To support new brand name and models and addition of adaptive symbol for consistency with symbol already used on other Medtronic labels

The following supporting information and data is provided in this PMA/S that substantiates safety and effectiveness of the Viva CRT-P system.

Firmware Description of Changes

The Viva CRT-P device firmware was modified to support the added and modified features. The changes made to currently-approved firmware functionality and the testing performed to support the safety and effectiveness of the modified firmware is included in **Non-Clinical Studies** section of this PMA-Supplement. Test results demonstrated that firmware functionality requirements were met.

Software Description of Changes

The Viva CRT-P device software application, the Model 9995 version 8.3, was modified to support the added and modified device features. Please refer to the Programmer Software in **Non-clinical Studies** section for detailed list of changes. The changes made to the currently approved software functionality and testing performed to support the safety and effectiveness of the new software is included in **Non-Clinical Studies** section of this PMA-Supplement. Test results demonstrated that the software application operates per specification and is ready for release. Please refer to the **Non-Clinical Studies** section for programmer software test reports.

User Interface Enhancements

On-Screen Cardiac Compass

On-Screen Cardiac Compass Report – provides graphs showing the patient’s condition over the last 14 months, such as frequency of arrhythmias, amount of physical activity, heart rates, device therapies, and fluid status. Please refer to **Non-Clinical Studies** section of this PMS/S for details.

On-Screen Rate Histograms and Percent CRT Pacing (Bi-V and LV)

Please refer to **Non-Clinical Studies** section of this PMS/S for details.

Manufacturing and Sterilization

The assembly processes used to manufacture the Viva CRT-P device are identical to the approved manufacturing methods used in the manufacture of the Consulta CRT-P device. An overview of manufacturing facilities, manufacturing flowchart, manufacturing changes and sterilization is provided.

Non-Clinical Studies

Based upon the similarities to previously approved Medtronic devices (Consulta CRT-P and Viva XT CRT-D), product safety and effectiveness has been demonstrated through comprehensive device and system level verification and validation bench testing in conjunction with complementary animal testing to demonstrate that the devices meet their specification in the intended environment. In addition, the safety and effectiveness is supported through prior clinical data.

Risk Management

Formal risk analysis and risk assessment for the Viva CRT-P system was conducted according to ISO 14971. The Viva CRT-P system was reviewed for potential hazardous scenarios that could result from the new feature additions

or modifications to the baseline legacy system. Risk control mitigations have been evaluated and confirm that all risks have been mitigated.

Biocompatibility

The biocompatibility of the tissue-contacting materials used in the Viva CRT-P device has been established in previous PMA applications. There has been no material or processing changes made in the manufacture of the Viva CRT- P device.

Packaging

The packaging configuration for the Viva CRT-P device is identical to that approved for the Consulta CRT-P device and has been qualified by equivalence.

Shelf Life

Packaged and sterile Viva CRT-P devices are labeled with an 18-month shelf life based upon qualification by equivalence to the Consulta CRT-P device.

Bibliography

This section of the submission provides summaries of the literature that are relevant to the Viva CRT-P device.

Labeling

The labeling for the Viva CRT-P device is based upon the approved labeling for Consulta CRT-P devices. Appropriate changes have been made to reflect the Viva CRT-P device model.

Clinical Investigations

Based upon the mechanical characteristics and the new and modified features that have been introduced into the Viva CRT-P device, product safety and effectiveness has been demonstrated through comprehensive system level verification and validation bench testing in conjunction with simulation testing (for certain features) to demonstrate that the device meets specifications in the intended environment.

In addition, the Adaptive CRT Clinical Study¹ investigated the safety and efficacy of the new AdaptivCRT feature. The AdaptivCRT feature provides patient-specific automatic and dynamic selection of left ventricular (LV) or biventricular (BiV) cardiac resynchronization therapy (CRT) pacing and adjustments of atrio-ventricular (AV) and interventricular (VV) delays based on periodic evaluation of intrinsic electrical conduction. This study passed all three of its primary objectives, demonstrating safety and effectiveness of the AdaptivCRT feature. Primary study objective results demonstrated the following:

- The AdaptivCRT feature is effective as determined by the clinical non-inferiority results of the Clinical Composite Score between the AdaptivCRT group and the Echo-Optimized Control group.
- The AdaptivCRT feature is effective as determined by the clinical non-inferiority of the cardiac performance results between the AdaptivCRT feature and the echo-optimized settings.
- The AdaptivCRT feature is safe as determined by the results from AdaptivCRT feature data. No inappropriate device AV or VV delays were found in the study.

Since all three primary endpoints were met, six pre-specified secondary endpoints were analyzed in a hierarchical fashion as planned. All six secondary endpoints were also met. The secondary objectives focused on other clinically relevant outcomes for heart failure patients and corroborated the results of the primary objectives. Furthermore, mortality and adverse event rates were similar between the two study groups.

In summary, the Adaptive CRT Clinical Study met all primary and secondary safety and efficacy endpoints demonstrating that the AdaptivCRT feature is safe and effective in the clinical environment. Safety and effectiveness is also supported through prior clinical data from FDA approved Medtronic devices. These data were used to support the Viva XT CRT-D PMA Supplement (PMA/S P010031/S318 approved January 29, 2013). Information on this clinical study is presented in the **Clinical Experience** section of this PMA Supplement.

Patient Management

The CareLink Monitor Model 2490G, CardioSight Reader Model 2020A, CareLink Express Model 2020B and the Device Data Management Application (DDMA) Model 2491 required some updates for the release of the Viva CRT-P device.

All testing for the CareLink Monitor Model 2490G, CardioSight Reader Model 2020A and CareLink Express Monitor Model 2020B were successfully completed. The analysis and testing performed demonstrates the 2490G, 2020B and 2020A software operate per specifications. The analysis and testing for the XMLTU demonstrated that the software in these devices operates per specification and no anomalies were observed.

REVIEW OF SUBMISSION

The submission was reviewed by the following team:

Reviewer	Items reviewed	Outcome / Recommendation
Ingmar Viohl (Lead Reviewer)	Biocompatibility, Verification & Validation (no software / firmware)	Acceptable (excluding sterility / bacterial endotoxin testing) *Additional information on endotoxin testing was considered acceptable.
Kim Selzman	Labeling	Acceptable
	Patient Management	Acceptable
	IFU	Acceptable
	Clinical Experience	Acceptable
Kosta Makrodimitris	Software	Need additional information *Additional information provided was considered acceptable
	Firmware	Need additional information *Additional information provided was considered acceptable
Erin Cutts	Biocompatibility	Acceptable
Elizabeth Gonzalez	Sterility	Deficiency: Bacteria endotoxin test missing *Additional information provided was considered acceptable. Minor Deficiency: Need information sterilization Qual. *Additional information provided was considered acceptable.
	Packaging	Acceptable (except above noted)
	Shelf Life	Acceptable (except above noted)
All	Executive Summary	Acceptable

*Additional information was provided by the firm in the form of amendment P010015 / S227 / A001. The review of the additional information provided showed it to be acceptable and retired any remaining concerns.

The key argument of this submission is that the hardware of the Viva CRT-P C6TR01 is identical to that of the Consulta CRT-P device model C4TR01. Changes are limited to the software and firmware of the device and external (non-implantable) equipment to support the introduction of the

- AdaptivCRT algorithm (AdaptivCRT)
- CardioSync Optimization Test
- On-screen Cardiac Compass
- On-screen rate histograms and percent CRT pacing (Bi-V and LV)

These features listed were approved as part of the Viva XT CRT-D device (P010031/S318, January 29, 2013). In addition to the introduction of these new features, the submission also includes a list of improvements and “bug fixes” to existing software. These span additional device models and as such need to go through verification / validation testing. The initial review of the submission showed test protocols and test reports missing. The information was requested from and provided by the firm. The additional information addressed the outstanding concerns.

Based on the fact that the hardware is identical to the cited predecessor device, with the exception of the IPG engraving, the firm argues that tests related to the manufacturing process, sterility, biocompatibility, etc. are passed by equivalence. Even though the reviewers fundamentally agree with this argument, documentation must be sufficient to evaluate the status of the predecessor device. The initial sterility review found several cited documents missing. The firm provided the documentation and it was found that the additional information provided addressed the concerns. A detailed review is given below.

Software Review

Initially the firm provided a brief description of the software and mentioned that there are relevant documents available upon request. We communicated to the firm that we needed to review adequate and organized software documentation according to FDA software guidance documents. We informed the firm that they should submit adequate software documentation according to MAJOR level of Concern (table 3 of the FDA software guidance) such as SRS & Traceability analysis (complete matrix with numbered line items for requirements, design specifications, risks and tests, and pointers to hazard mitigations).

The firms indicated in the submission that the following test were executed and reports are available for

- AdaptivCRT CRT-P Software XMLTU Verification Test Results Report
- AdaptivCRT CRT-P Software Programmer Verification Report

The firm was asked to provide these reports or at least the description and acceptance criteria of the tests related to the changes of the software of this proposed device. The firm did so with the amendment.

The firm used several references and traces to the IEC 62304: 2006 and ISO 13485: 2003 standards regarding the software of submitted device (Software Development Life Cycle, Verification strategy, Validation, Traceability etc.). The initial submission did not provide documentation showing compliance to these standards. The firm was asked to provide a comprehensive documents or reports that show compliance to specific sections/clauses of the above standards. The firm provided the documentation as part of the amendment.

The firm reported two minor anomalies (b)(4) TS/CCI) for the software according to the software verification of the proposed device. However, these anomalies did not result in any relevant labeling changes, for example updates to user manuals, to inform the physician or patient of these or other software or user interface issues. When asked, the firm indicated that both anomalies were discussed in Section 9.3 Subsystem Testing, AdaptivCRT CRT-P Software Justification Table (b)(4) TS/CCI which described each anomaly, resolution, and rationale for either disclosing or not disclosing the anomaly in an errata sheet (Volume 2, Programmer Software, page 2-28). Based on the Software Anomaly Categorization Process, Software (b)(4) TS/CCI software had one (1) anomaly (b)(4) TS/CCI that met the criteria for inclusion on the Errata Sheet, which was provided in the Labeling section (Volume 5, page 5-134). The Errata Sheet provides a description of the anomaly and corrective action for resolution. The rational provided in the amendment was accepted.

FIRMWARE

The firm provided a brief description of the firmware and indicates that there are relevant documents available upon request. We informed the firm that we need to review adequate and organized firmware documentation of this submission according to FDA software guidance documents. We asked the firm to submit adequate firmware documentation according to MAJOR level of Concern (table 3 of the FDA software guidance) such as SRS & Traceability analysis (complete matrix with numbered line items for requirements, design specifications, risks and tests, and pointers to hazard mitigations).

The firm indicated in the amendment that documentation relevant to the respective firmware changes for the Viva CRT-P device are distributed throughout the firmware documents identified in the PMA/S, Volume 2 Sub-System Verification Testing. As noted in this section, some of the documents are very large, and only the tables of contents were provided. Per FDA's request, the following documents are provided in their entirety (electronic format only in folder labeled "MISC FILES" on the CD-ROMs) and support the firmware changes of the Viva CRT-P device. The

firm indicated that (b)(4) TS/CCI is also noted in the firmware section. The table of contents was provided, as this document is 3833 pages. Since this document is related only to the legacy device features and not the new features specific to the Viva CRT-P device, it is not provided.

- Attachment 6: (b)(4) TS/CCI Device Requirements Specification (b)(4) TS/CCI
- Attachment 7: (b)(4) TS/CCI CRT-P Firmware Design Specification (b)(4) TS/CCI
- Attachment 8: AdaptivCRT CRT-P Firmware Verification Traceability Report (b)(4) TS/CCI

In the attempt to explain the organization of the firmware documentation in terms of what each document provides and how they relate to each other, Medtronic provided a traceability example that demonstrates verification of a representative subset of the firmware changes for the proposed device. The example is provided as Attachment 9 of the amendment. The submitted documentation and explanations were found to be acceptable.

The firm initially provided an AdaptivCRT CRT-P Firmware Verification Test Summary Report. However it was not clear from the tables (DRD test results) what the (b)(4) TS/CCI Feature (VT feature group that was tested) were. We asked the firm to provide a description of the feature(s) tested and the acceptance criteria for each test by focusing mainly on the feature changes (or affected) and their respective tests.

The firm indicated that the DRD test results table is a comprehensive list of all the test groups executed as part of formal verification of the firmware. The entire set of Gen-2 device firmware verification tests was re-executed except for a small subset listed in section 3.2.2 of the AdaptivCRT CRT-P Firmware Design Plan Addendum (b)(4) TS/CCI (Volume 2). VT feature groups with updated tests due to interactions with the firmware updates include Emergency VVI ((b)(4) TS/CCI), firmware scheduler (Scheduler), pacing feature contentions (Pace_Contentions), pacing feature pertinencies (b)(4) TS/CCI, patient activated episodes EGM (b)(4) TS/CCI and device reset (b)(4) TS/CCI. All of the tests for new features AdaptivCRT, CRT Optimization Test, and Percent CRT Pacing are found in the VT feature group "Adaptive_CRT". The new tests for the Legacy Input analysis firmware updates are found in VT feature group (b)(4) TS/CCI. All test scripts are set up to have pass/fail criteria for all verification steps, and 100% pass is required. The AdaptivCRT CRT-P Firmware Verification Traceability Report (b)(4) TS/CCI (Attachment 8) lists all of the requirements and associated test cases and test scripts. An excerpt from the traceability report and an example test case are provided in Attachment 9 of this amendment.

All firmware changes are subject to thorough verification throughout the Firmware Development Life Cycle. The AdaptivCRT CRT-P Firmware Design Plan Addendum specifies the Firmware Development Life Cycle, the firmware design artifacts associated with each Life Cycle step, and the associated Acceptance Criteria for the verification activity for each design artifact. Verification records for the incremental verification activities that occur throughout the development life cycle are contained in change reports in an issue tracking system (ref. AdaptivCRT CRT-P Firmware Design Plan Addendum, section 5.4.3). The final verification step is the Verification of the Finished (firmware) Product which is responsible for verifying the final firmware image meets the associated Firmware requirements. The firm's response was considered acceptable.

The firm provided some brief information about security (design, standards) for the proposed device. However the firm did not provide cybersecurity measures (risks, controls, design and verification) in the submission. The device may pose safety and security risks for patients (CardioSight and CareLink Network, network installation, monitoring, telemetry etc.). We asked the firm to provide security controls (limit access to trusted users, ensure trusted content, fail safe and recovery options etc.) to assure medical device cybersecurity: information confidentiality, integrity, and availability.

The firm indicated that security is a system-wide property, and each of the subsystems is responsible for a portion of the overall system security. The specific controls for confidentiality, integrity, and availability are called out for the major subsystems below.

Implanted Device

- Proximity based inductive telemetry communications rely on physical proximity for ensuring confidentiality and availability. The inductive telemetry used by implanted medical devices to communicate with programmers and remote monitors have a defined limited range, and it is assumed that the patient has reasonable awareness and control over their immediate physical environment. This model is the same model employed by getting a flu shot, where intimate patient contact is required to administer care.
- Proximity telemetry communications use a protocol that includes CRC-integrity checks to ensure the integrity of the data communications.
- The telemetry protocol includes integrity checks at the (b)(4) TS/CCI layer to verify the integrity of the communication.
- The implanted device is designed with fail-safe features such as periodic memory integrity checks on critical memory regions to ensure patient safety. If an error is detected, the device will perform a reset and return to a known configuration.

Home Monitors

The MyCareLink Home Monitor incorporates the following information security controls:

- The home monitor initiates all network communications and rejects any incoming connections eliminating a potential attack vector.
- Communications occur over the public internet and confidentiality is provided using (b)(4) TS/CCI .
- Communications occur over the public internet and integrity is provided using the (b)(4) TS/CCI .
- The MyCareLink Monitor authenticates the server via a certificate as part of the (b)(4) TS/CCI establishment.
- Sessions from the monitor to Medtronic are established only after authentication (b)(4) TS/CCI , which occurs inside the (b)(4) TS/CCI . Credentials are unique per-monitor and randomly generated.
- In addition to the (b)(4) TS/CCI at the transport layer, all patient data is encrypted at the application layer using (b)(4) TS/CCI to provide confidentiality and integrity.
- All software updates are digitally signed and encrypted when in transit from CareLink to the monitor.
- All MyCareLink monitors utilize CareLink infrastructure security controls to monitor for abnormal activity. Controls include Data Loss Prevention (DLP) tools, Security Incident Event Management system, Intrusion Detection/Prevention Systems, firewalls and load balancing technologies to detect, alert and prevent where possible abnormal activity

2490 Home Monitors incorporates the following information security controls:

- The home monitor initiates all network communications and rejects any incoming connections eliminating a potential attack vector.
- Communications occur over private networks dedicated to Medtronic via dialup and machine-to-machine networks.
- Access to the networks is controlled and authenticated by Medtronic
- Communication sessions from the monitor to Medtronic are authenticated using (b)(4) TS/CCI authentication. Credentials are unique-per-monitor and randomly generated.
- Confidentiality and integrity of patient data is provided by the (b)(4) TS/CCI encryption protocol at the application layer using a (b)(4) TS/CCI
- All 2490 monitors utilize CareLink infrastructure security controls to monitor for abnormal activity. Controls include Data Loss Prevention (DLP) tools, Security Incident Event Management system, Intrusion Detection/Prevention Systems, firewalls and load balancing technologies to detect, alert and prevent where possible abnormal activity.

Programmers

Encore Programmers incorporate the following security controls:

- The programmers are a dedicated medical instrument and are not general purpose computers and are used within a controlled clinical setting.
- The programmer was designed to limit access to only the required medical device application functionality. The programmers do not allow browsing the internet, checking email, or running office applications. It is not possible for a user to browse the file system or execute arbitrary programs.
- USB media may be used, but restrictions are in place to prevent execution from the USB media used and to limit the files that may be accessed to only those files that have a clinical use on the programmers.
- All software updates on USB media (b)(4) TS/CCI .
- As a result of these limitations, the programmers do not have most of the common attack vectors associated with malicious software.
- Confidentiality of patient data on the Encore programmer is provided by encrypted storage
- Patient data availability is limited by automated processes to wipe the patient data.
- Network communications of the programmers may be initiated under some circumstances to provide benefits to the user. Situations are for software updates, remote viewing of the Encore screen or connection to provider's Paceart systems. Confidentiality is assured in all communications methods by using a minimum of (b)(4) TS/CCI .
- Network communications for software updates are authenticated by unique-per programmer credentials (unique certificates and username/password).
- Network communications for remote viewing and Paceart include authentication through (b)(4) TS/CCI .
- Firewalls are used to protect the system from unsolicited communications.
- The programmer is designed to allow unfettered access to support emergency use situations. No passwords are required.
- The programmer boot process is designed to ensure that it always boots from a known, good state.

2090 programmers incorporate the following security controls:

- The programmers are a dedicated medical instrument and are not general purpose computers and are used within a controlled clinical setting.
- The programmer was designed to limit access to only the required medical device application functionality. The programmers do not allow browsing the internet, checking email, or running office applications. It is not possible for a user to browse the file system or execute arbitrary programs.
- USB media may be used, but restrictions are in place to prevent execution from the
- USB media used and to limit the files that may be accessed to only those files that have a clinical use on the programmers.
- Patient data availability is limited by automated processes to wipe the patient data.
- As a result of these limitations, the programmers do not have most of the common attack vectors associated with malicious software.
- Network communications of the programmers may be initiated under some circumstances to provide benefits to the user. Situations are for software updates, remote viewing of the 2090 screen or connection to provider's Paceart systems. Confidentiality is assured in all communications methods by using a minimum of (b)(4) TS/CCI .
- Network communications for software updates are authenticated by unique-per programmer credentials (username/password).

- Network communications for remote viewing and Paceart include authentication through (b)(4) TS/CCI.
- Firewalls are used to protect the system from unsolicited communications.
- The programmer is designed to allow unfettered access to support emergency use situations. No passwords are required.
- The programmer boot process is designed to ensure that it always boots from a known, good state.

CareLink Network

- CareLink Network is ISO-27001 certified which demonstrates adherence to international information security standards.
- CareLink uses role-based access to ensure confidentiality and limit availability to authorized users only. A clinic-patient relationship is established at implant.
- CareLink data transmissions utilize (b)(4) TS/CCI encryption to ensure confidentiality and integrity throughout the transmission process.
- Data stored within CareLink database is encrypted and access is controlled through role-based access.

CareLink has implemented monitoring such as Data Loss Prevention (DLP) tools, Security Incident Event Management system, Intrusion Detection/Prevention Systems, firewalls and load balancing technologies to detect, alert and prevent where possible abnormal activity.

The information provided by the firm with respect to cyber security was found to be acceptable.

Sterility Review

The firm indicated that results from the predecessor device (here Consulta CRT-P C3TR01) are leveraged. The device labeling is not clear. The US model number for the Viva CRT-P is C6TR01, whereas the OUS model is C5TR01. Firm needs to clarify if the OUS predecessor device is the Consulta CRT-P C3TR01 and the US model is C4TR01. The firm indicated in a discussion that the FDA interpretation is correct, i.e., the CRT-P C3TR01 is the OUS model but does not physically differ from the CRT-P C4TR01.

The firm initially stated that they did not perform bacterial endotoxin testing either on the new Viva CRT-P devices or on the previous Consulta CRT-P devices citing an internal memo: (b)(4) TS/CCI saying that “implantable devices, like Viva CRT-P product models, do not directly contact blood, lymphatic, or cerebrospinal fluid.” In FDA’s view, the Viva CRT-P devices are covered in the June 2012 “Guidance for Industry Pyrogen and Endotoxins Testing- Questions and Answers” as subcutaneously implanted device for which endotoxin test limits have been established according to section 11 for the Guidance document: “*The endotoxins limit for a medical device is dependent on the intended use of the device and what the device contacts (e.g., blood, the cardiovascular system, cerebrospinal fluid, intrathecal routes of administration, permanently implanted devices, and device implanted subcutaneously)*”. The firm was asked to provide the quoted memo (b)(4) TS/CCI bacteria endotoxin test data for the Viva CRT-P devices or substantial rationale why it is not needed on a device by device case as well as details of the routine monitoring that will occur.

The firm provided the referenced internal memo (b)(4) TS/CCI as well as the following rationale:” *Medtronic controls microbiological quality in a fashion that ensures the presentation to the sterilization process of product with a consistent controlled and understood level of microbial contamination. This is based on the approach that maintaining and demonstrating a strict microbiological control of the facility manufacturing environment (CEA) and product manufacturing processes are most appropriate and effective at controlling all microbial contamination including bacterial endotoxin. Medtronic CEA environmental monitoring and product bioburden testing practices are among the most aggressive in the medical device industry.*

The description of endotoxin-mediated pyrogens in ISO 10993-11:2006 states that contamination usually occurs during the manufacturing process. ANSI/AAMI/ST72:2011 Section B.10.3.2 states “Dry products that are produced under high temperatures or in controlled environments do not normally present the same risk of endotoxin contami-

nation as a “wet” process in which water is present in the process.” The manufacturing process (shown in the Sterilization Qualification Rationale) for the Viva CRT-P devices is primarily a dry process and is not conducive to endotoxin contamination to occur for the following reasons:

(b) (4) TS/CCI

As described, the current manufacturing process as well as the environmental controls in place at Medtronic manufacturing facilities appropriately minimize the risk of endotoxin contamination. Medtronic’s position is based upon the contention that maintaining and demonstrating strict microbiological control of the manufacturing environment and manufacturing process is an adequate preventative measure for bacterial endotoxin contamination.”

The rationale provided by the firm in conjunction with the fact that the changes made to the predecessor device are only software related is sufficient to address the endotoxin concern.

In the initial submission the sponsor stated that in (b)(4) TS/CCI process was qualified for sterilization using the (b)(4) TS/CCI on (b)(4) TS/CCI . The firm cited ISO 11135 and referenced an internal protocol, (b)(4) TS/CCI . It was unclear whether this memo or the details of (b)(4) TS/CCI method were included in the original submission. The firm was asked to provide details of how (b)(4) TS/CCI the bacteria was done during the sterilization qualification using (b)(4) TS/CCI method including the amount of bacteria used and where the bacteria (b)(4) TS/CCI . The firm indicated in the amendment that the details of (b)(4) TS/CCI method used for both the initial (b)(4) TS/CCI and annual requalification activities (b)(4) TS/CCI are documented in the Product Sterilization Qualification Rationale for Viva CRT-P Product Family (b)(4) TS/CCI that was provided in the PMA/S submission (Volume 1, Manufacturing and Sterilization). This report includes a description of how the (b)(4) TS/CCI done, the amount of bacteria used, and location of bacteria (b)(4) TS/CCI . Please refer to Section 9.0, page 13, Product Adoption Details of this report. The firm’s clarification was sufficient to address the originally posed question.

OAI Firm & Corporate-wide Warning List was checked on December 23, 2013 and the document was found to be clear. A subsequent check on July 02, 2014 gave the same result.