Summary of: P890003/S285, P090013/S112, P010031/S397, P010015/S215, P980016/S436, P980035/S343

Background and Summary

This PMA Supplement is to obtain approval for updates to the Medtronic MyCareLink™ Patient Monitor Model 24950, Reader Model 24955, and accessories, Model 2491 Device Data Management Application (DDMA) and Application Software SW026 to support Medtronic's Reveal LINQ Insertable Cardiac Monitors (ICM). It is being submitted in conjunction with K132649 for related changes to the Reveal LINQ Model LNQ11 Insertable Cardiac Monitor which is currently under review. The intended use for the supporting instruments included in this submission remains as currently approved.

Changes included in this submission are described in this memo. These changes were predominately related to software, firmware, and wireless technology. The changes were verified and validated through a GLP animal study and human factors study.

Several issues arose during the first round of review regarding the wireless technology, software, animal study, and human factors. Deficiencies were sent to the sponsor in a Major Deficiency Letter on November 13, 2013. These deficiencies were addressed Amendment 1. All issues were resolved in Amendment 1.

Coordination of the approval of this supplement and clearance of K132649 is necessary, as the ICM cannot function without the MyCareLink monitor. Therefore, approval of this supplement is recommended based on the fact that the lead reviewer of K132649 plans to clear the 510(k).

Device Description

The Medtronic MyCareLink™ Patient Monitor Model 24950, Reader Model 24955, and accessories, Model 2491 Device Data Management Application (DDMA) and Application Software SW026 support the Medtronic Reveal LINQ™ Insertable Cardiac Monitor. This is a programmable device which continuously monitors a patient's ECG and other physiological parameters. The Reveal LINQ ICM records cardiac information in response to automatically detected arrhythmias and patient activation.

The Reveal LINQ ICM is designed to automatically record the occurrence of arrhythmias in a patient. Arrhythmia may be classified as atrial tachyarrhythmia/atrial fibrillation (AT/AF), bradyarrhythmia, asystole, or (fast) ventricular tachyarrhythmia. In addition, the Reveal LINQ ICM can be activated by the patient to record cardiac rhythm during symptomatic episodes.

The following devices are included in the Reveal LINQ system:

- **Medtronic Reveal LINQ Model LNQ11 Insertable Cardiac Monitor** – The Reveal LINQ device, packaged with incision tool and insertion tool, is a small, leadless device that is implanted under the skin, in the chest. Two electrodes on the body of the device continuously monitor the patient's subcutaneous ECG.
- **Medtronic CareLink Model 2090 or Encore Model 29901 programmer with Reveal LINQ software** – The programmer is used to set up the device to detect arrhythmias. It also allows the clinician to view, save, or print the stored information.
- **Reveal Patient Assistant Model 9538** – The Patient Assistant is a hand-held, battery-operated telemetry device that enables the patient to record cardiac information in the Reveal LINQ device after experiencing symptoms of a possible cardiac event.
- **Medtronic MyCareLink Home Monitor Model 249050** – The MyCareLink home monitor is a wireless data receiver used to automatically receive information from the Reveal LINQ device. It also allows the patient to perform full device interrogations using telemetry, and automatically communicates data onto CareLink.
- **Medtronic CareLink Network –** The CareLink network is used to store, display and report diagnostics data.

Changes included in this submission are described below. These changes were predominately related to software, firmware, and wireless technology. The changes were verified and validated through a GLP animal study and human factors study. This information is reviewed below.

Software

Medtronic CareLink Model 2090/Model 29901 Programmer with Model SW026 Software

Changes to the Application Software Model SW026 include the following:

- Modification to information gathered at implant, adding: patient address, second phone, gender, physician specialty, and implant location
- Enhancement to programming setup by adding a Reason for Monitoring which auto sets parameters to suggested values for patient indication
- Enhancement to program the Tachy rate based on patients age. (rate=230-age)
- Modification to “Asystole” renamed as “Pause”
- Modification to “FVT/VT” renamed pairing as “Tachy”
- Removed FVT programming; rate is fixed at 260ms, Duration is fixed at 30/40 beats (VT parameters are still programmable)
- Removed VT Onset and VT Stability programming: This is not a major change and would not affect the safety or effectiveness of the device.
- New programming settings Wireless Transmission Time and Wireless Data Priority used to setup new daily wireless transmissions.
- Enhanced Reports to include 5 lines of ECG/page
- Removed Patient Assistant Setup programming.
- Removed ECG filter programming on stored episodes view (filter is always applied).
- Enhancement to support Unicode for patient information
- Updated interrogation request to match FW changes
- Minor User Interface (UI) and report layout changes to improve ease of use.
- Removed Support for Flex Configuration
- Minor Interlock and Observation Updates
- Longest AF Only Mode. Provides the ability to store only the Longest AF Episode that is greater than 10 minutes in duration between sessions.

Level of Concern

The Level of Concern is Major for the Model SW026 Application Software: A failure or latent flaw could directly result in death or serious injury to the patient. The software provides diagnostic information that that is used by physicians along with patient symptoms to drive decisions regarding treatment or therapy such that if misapplied it could result in serious injury. ***This information is acceptable.***

Software Requirements Specification

The sponsor provided the Model SW026 requirements in the Reveal Software Requirements Specification (b)(4) Trade Secret/CCI in Attachment 2 of the original submission.

LEAD REVIEWER COMMMENTS: It was unclear which requirements have been changed as a result of the modifications proposed in the original submission. The following deficiency was sent to the sponsor in the November 11, 2013 Major Deficiency Letter:

You have provided the software requirements for Model SW026 in Attachment 2 of your submission. However, it is unclear which requirements have changed as a result of the modifications proposed in the submission. Please provide a list of requirements that are new to the software requirements specification or those that have changed as a result of the modifications proposed. Alternatively, please provide a redlined version of your requirements specification.

The sponsor has provided a list of enhancements/updates to the software, traced to the specific section in the SRS where the requirements pertaining to these updates are found, and the type of change. All modifications introduced in this submission have corresponding software requirements. I have no concerns with the changes made to the SRS as a result of the software modifications. ***This information is acceptable.***

Device Hazard Analysis

The device hazard analysis/risk analysis is provided in the Injectable Reveal LINQ Summary Risk Management Report (b)(4) Trade Secret/CCI in Attachment 3 of the original submission. It should be noted that this report includes all aspects of the system, including the Reveal LINQ insertable cardiac monitor and is not specific to any subsystem. The analysis was developed in accordance with ISO 14971 Risk Management Process.

The sponsor concludes that all Reveal LINQ residual risks were reduced to Class I or Class II risk level. Overall risk is considered low and acceptable. The sponsor has not provided a full hazard log and will be asked to do so.

LEAD REVIEWER COMMENTS: The following deficiency was sent to the sponsor:

You have provided a device hazard analysis/risk assessment in Attachment 3 of your submission. In this report, you reference the Reveal LINQ Hazard Analysis Log, however you have not provided this document. This is important to ensure that all hazards have been appropriately identified, categorized and mitigated. Please provide this Hazard Analysis Log including each hazard identified within the system, the severity of each hazard, possible causes of each hazard, methods of control, design/requirements that eliminate, reduce, or warn of a hazardous event, and verification that the method of control was implemented correctly.

The sponsor has provided the Reveal LINQ Hazard Analysis Log in Attachment 1 of P890003/S285/A001. Note that this include hazards associated with the programmer changes but also hazards associated with the ICM. Hazards have been appropriately assessed, mitigations are in place, and verification has been performed to ensure that these mitigations are efficient. The only hazard that has been identified as Class III (very high risk) is contamination due to implant in less-sterile environment. This is related to the ICM implant procedure, and does not directly affect the programmer or changes described in this submission. I will defer to the review of the ICM in K132649. Therefore, I find the hazard analysis acceptable and have no further concerns.

Architecture Design Chart

The Model SW026 version 8.0 application software is based on the Model SW007 v.7.1 Software (P890003/S209, approved 4 May 2011). The software architecture document (CRM Vision Software Architecture Description Attachment 4) provides a decomposition and analysis of the Model SW026 Software architecture, including rationale supporting the choice of architecture and design strategies used. The software architecture was updated for the modifications proposed in this submission to include updates to Language DLL's naming mechanism for Unicode.

LEAD REVIEWER COMMENTS: The software architecture has not been significantly affected by the changes proposed in this submission. The only modification made was to incorporate Unicode into the architecture. This does not seem to affect the device safety or effectiveness and I have no concerns with this update. This information is acceptable.

Traceability Analysis

The sponsor has provided the SW Verification Trace Report in Attachment 6 of the submission. In this document, the sponsor has described the trace activities performed to ensure that all software requirements can be traced to verification activities. For example, a trace was performed on the "Injectable Reveal Software Requirements Specification" and the Verification Test Specification "Application VTS". This activity showed that all software design requirements have a matching requirement in the verification test specification with no discrepancies.

LEAD REVIEWER COMMENTS: Although this is not the typical form of a traceability analysis, I believe this is acceptable. The sponsor has demonstrated that all requirements can be traced to verification activities. I consulted with a software expert on this matter and she finds this type of analysis acceptable as long as the sponsor demonstrated that all requirements have been tested. The sponsor has demonstrated this and therefore, I have no further concerns.

Software Development Environment Description

The Injectable LINQ Reveal Software Development Plan (b)(4) Trade Secret/CCI presented in Attachment 5, defines the overall strategic plan and processes to be followed by the Reveal LINQ Software team for the verification activities associated with the Model SW026 Software application. This plan includes the life cycle model used for the project (section 7.1), processes followed, and responsibilities of the project team and coding practices for the project (section 6). Software configuration management is outlined (section 9.2) in the plan. The database system (SCR System) that is used to track changes to deliverables is also detailed (section 7.2.2).

> *LEAD REVIEWER COMMENTS: The sponsor has done a good job of defining the software development environment including life cycle processes and how changes are managed, as well as other aspects of the environment. This information is acceptable.*

Software Verification

Requirements-based testing was performed at sub-system level and at system level. The software (sub-system) verification test is a (b)(4) Trade Secret/CCI primarily ensures that the fully integrated Model SW026 Software operates as prescribed. For each requirement one or more tests were designed and executed. (b)(4) Trade Secret/CCI Besides requirements-based testing, stress testing and installation testing were also executed. The (b)(4) Trade Secret/CCI Attachment 9 provides detailed information regarding the strategy and approach of the software verification tests.

All issues detected during the software verification tests were reported and minor anomalies were deemed acceptable. After completion of the verification testing, the (b)(4) Trade Secret/CCI (b)(4) Trade Secret/CCI Attachment 7 was generated.

> *LEAD REVIEWER COMMENTS: The verification testing for the SW026 software is adequate. There were 24 failures found during the testing that resulted in 5 unresolved, acceptable anomalies. The other 19 failures were either fixed or a result of test structure or documentation and I am not concerned with these failures. The 5 unresolved anomalies are described in further detail in the Unresolved Anomalies section below.*

Unresolved Anomalies

During the verification and validation testing listed above, there were a total of twelve (12) anomalies found pertaining to the Medtronic SW026 version 8.0 Software application. The (b)(4) Trade Secret/CCI in Attachment 20 identifies any anomalies that were resolved by determining them to be acceptable. A test issue description and rationale for each accepted test issue is outlined. Errata inclusion and rationale is also provided.

> *LEAD REVIEWER COMMENTS: The sponsor included the twelve (12) anomalies found in the verification and validation activities in Attachment 20 for further clarification. All*

anomalies are found to be acceptable and I agree with this assessment. The anomalies found will most likely cause some user inconvenience but will not affect patient safety or device effectiveness. None of the anomalies will be included in the Errata sheet, and I do not believe they need to be. I have no further concerns with the unresolved anomalies and find this information acceptable.

Medtronic MyCareLink Home Monitor Model 249050/Model 24955 and accessories

This section provides software information regarding the Model 24950 MyCareLink Patient Monitor and Model 2491 DDMA that support the Reveal LINQ ICM. The MyCareLink home monitor is a wireless data receiver used to automatically receive information from the Reveal LINQ device. It also allows the patient to perform full device interrogations using telemetry, and automatically communicates data onto CareLink. The Device Data Management Application (DDMA) is the modular network-resident component of the MyCareLink Monitor system. The DDMA consists of three components: the XML Translation Utility (XMLTU) was created for this system. The Session Data Decode Utility (SDDU), Deconvolution Algorithm, and PWF are not applicable to this device.

Changes to the MyCareLink Model 24950, Model 24955 and accessories:

- Modified RFM (radio frequency module) RAMware to listen for daily wireless data transmissions
- Added the MyCareLink Monitor LINQ app to support the LINQ device
- Added new package reconstruction algorithm to assemble incoming wireless transmission data
- Added patient notification message to indicate if patient needs to phone physician; feature previously existed within patient assistant
- Updated interrogation requests to match FW changes
- Resolved an issue wherein the monitor USB driver that supports the cellular modem becomes unresponsive

Changes to the DDMA Model 2491:

- Updated XMLTU to support wireless transmission data
- PWF (b)(4) Trade Secret/CCI ECG is (b)(4) Trade Secret/CCI on all interrogations and is translated through the XMLTU

Level of Concern

The level of concern for the MyCareLink monitor and associated software was not provided in the submission. Therefore, the sponsor was asked via e-mail to address this. The sponsor indicated, via e-mail response on November 4, 2013 that, per the FDA guidance document titled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", dated May 11, 2005, the level of concern pertaining to the software on the MyCareLink Patient Monitor, Models 24950 and 24951 is major. This is because the

MyCareLink Patient Monitor serves as an accessory to Medtronic implantable medical devices (IPGs, ICDs, CRT-IPGs, CRT-ICDs and ICMs).

LEAD REVIEWER COMMENTS: I agree with the sponsor's assessment that the MyCareLink monitor should be classified as a major level of concern. This information is acceptable.

Software Requirements Specification (SRS)

The product requirements specification for this project is:

- (b)(4) Trade Secret/CCI for the Model 24950 MyCareLink Home Monitor Attachment 26

The software/firmware requirements specifications for this project are:

- (b)(4) Trade Secret/CCI Attachment 27
- (b)(4) Trade Secret/CCI Attachment 43

LEAD REVIEWER COMMENTS: Only minor changes have been made to the requirements specification as a result of the modifications described in this submission. Although I will ask the sponsor to provide more details regarding the requirements for the Model SW026 software (reviewed above), I do not think this is necessary for the MyCareLink software because of the nature of the modifications. I have no further concerns.

Device Hazard Analysis

Please refer to the Device Hazard Analysis section in the Model SW026 software review on Page 4 of this memorandum.

Architecture Design Chart

The sponsor provided the Architecture Design Chart for the MyCareLink monitor via e-mail on November 5, 2013. This document can be found in Attachment 1.

LEAD REVIEWER COMMENTS: There have been no changes made to the architecture of the software as a result of the modifications described in this submission. Therefore, I have no concerns with this document. This information is acceptable.

Traceability Analysis

Please refer to the Traceability Analysis section in the Model SW026 software review on Page 5 of this memorandum.

Software Development Environment Description

The sponsor has provided a description of the development environment for the MyCareLink monitor in (b)(4) Trade Secret/CCI Attachment 21. The development environment for the DDMA Model 2491 is described in (b)(4) Trade Secret/CCI Attachment 5. Similar to the software development environment description for the Model SW026 software described in the sections above, the development plans for the MyCareLink monitor and the DDMA Model 2491 define the overall strategic plan and processes to be followed by the Reveal LINQ Software team for the verification activities associated with these devices. These plans include the life cycle model used for the project, processes followed, and responsibilities of the project team and coding practices for the project. Software configuration management is outlined in the plan. The database system (b)(4) Trade Secret/CCI that is used to track changes to deliverables is also detailed.

> *LEAD REVIEWER COMMENTS: The sponsor has done a good job of defining the software development environment including life cycle processes and how changes are managed, as well as other aspects of the environment. This information is acceptable.*

Software Verification

Test specifications were created from the requirement specifications. Tests were written to exercise the firmware and software and to assure the requirements were fulfilled in the delivered product. Use-case testing emulated end-user scenarios which were executed using the production-equivalent configurations of system components. Through the execution of the test specifications, the user needs were tested. Use-case testing was repeated on iterations of the software as required throughout the development cycle.

The (b)(4) Trade Secret/CCI Test Report in Attachment 33 of the submission shows the results of the software verification. Three formal test runs were executed for this software. During the first run, eight (8) tests failed. A new software build was created for run 2. All tests passed in both run 2 and run 3. No new anomalies were found during this testing. Verification testing has shown that (b)(4) Trade Secret/CCI Software installable build meets the requirements of the project software requirements specifications and is acceptable for release.

> *LEAD REVIEWER COMMENTS: The software verification for the monitor software is adequate. The final run of the verification incorporated all changes made in the first two runs and showed that all tests passed. I have no further concerns.*

Clinical Review

Changes made to the Reveal LINQ System were reviewed by a clinician under K132649. The clinician reviewed these changes from a clinical standpoint and based on his review, did not have safety or effectiveness concerns. I leveraged the clinician's review for my review of the changes made to the software; all changes included in the subject submission were addressed by the

clinician in his review of K132649 and found to be acceptable. Therefore, I have no further concerns regarding the clinical implications of the software modifications in this submission.

Wireless Technology Review

The (b)(4) Trade Secret/CCI Telemetry operates under the low power/low duty cycle provisions of the (b)(4) Trade Secret/CCI. The low power/low duty cycle provisions allow a device to transmit for (b)(4) Trade Secret/CCI

The Reveal LINQ Radio-Frequency Module (RFM) RAMware listens (b)(4) Trade Secret/CCI. The RFM RAMware has two basic operating states: (b)(4) Trade Secret/CCI

If the received transmission contains errors, the monitor attempts to correct the errors using data from additional transmissions made during that day. The home monitor continuously listens for transmissions to forward to the CareLink patient management system. (b)(4) Trade Secret/CCI

RAMware Review

Injectable Reveal Master RFM Ramware will be used by the CRDM business unit within Medtronic.The ramware is developed to run on the (b)(4) Trade Secret/CCI microprocessor. The ramware adds new features (b)(4) Trade Secret/CCI, which is a part (b)(4) Trade Secret/CCI (b)(4) Trade Secret/CCI. (b)(4) Trade Secret/CCI functionality is being modified by this ramware.

The sponsor has provided the (b)(4) Trade Secret/CCI in Attachment 30 of the original submission. The purpose of this document is to define the (b)(4) Trade Secret/CCI test cases. It will also describe the results of the execution of all the integration tests that implement the test cases. The test report shows 50/50 test cases passed.

> *LEAD REVIEWER COMMENTS: the documentation provided to support changes to the RAMware are adequate. This information was reviewed in the first round of review and found to be acceptable.*

Quality of Service

The Reveal LINQ ICM does not provide real time critical alarms, continuous waveforms, control of therapy, or time-critical telemetry. The impact of interference is minimal due to the lack of real-time information. The system also transmits the same data multiple times per day and uses forward error correction to improve the link reliability.

The device generates a new summary report each day. Therefore, the data received by the monitor after one or more days of unsuccessful receptions will be the current data. The CareLink system will alert the clinician if data is not received on a given number of consecutive missed days so that that clinician can work with the patient to correct the problem.

LEAD REVIEWER COMMENTS: The quality of service described by the sponsor is adequate. However, the following deficiency was sent to the sponsor regarding lost data in the November 2013 Major Deficiency Letter:

> *Based on your description of the wireless technology included in your e-mail sent October 31, 2013, the MyCareLink Home Monitor generates a new summary report each day. Data received by the monitor after one or more days of unsuccessful receptions will be the current data. It is unclear what happens to data gathered on the days when transmission is not successful (i.e. if it is lost). This is important to understand if there are any risks to the patient safety or device effectiveness as a result of this lost data. Please clarify if this data is lost in place of the current data. If so, please justify any risks to patient safety as a result of this lost data.*

The sponsor provided a response to this deficiency in Amendment 1. The sponsor clarifies that data that is not successfully transmitted from either the device to the MyCareLink monitor or from the MyCareLink monitor to the CareLink server is not completely lost. It can be retrieved by requesting the patient to perform a manual transmission. This remains consistent with the functionality of the previous programmer system. If data is not successfully transmitted on a given day, the device has a 14 Day retransmission of that same data. If that data is not successfully transmitted after 14 days, the clinician will be notified by the system. Once notified, the clinician has the ability to request a manual transmission and obtain all the data from the device. Given this, there is a possibility of gap in data for up to 14 days, however, this is not concerning because the standard of care is a monthly follow-up. I believe the sponsor has adequately addressed this deficiency and do not have any concerns with this information. The data transmission can be made through manual means if necessary and clinicians are alerted when this is needed. The delay in data will hypothetically be no more than 14 days, which is less than the standard of care of a month. This information is acceptable.

Wireless Range Verification Testing

System verification testing for the wireless range of the Injectable Reveal system per (b)(4) Trade Secret/CCI (Attachment 12 of the original submission) was carried out. A total (b)(4) Trade Se monitors

were used, each of which (b)(4) Trade Secret/CCI analyzed. This test was (b)(4) Trade Secret/CCI which totaled (b)(4) Trade Secret/CCI. Of the (b)(4) Trade Secret/CCI were successfully received by the monitor and transmitted to the CareLink system equating to a 96% success rate.

LEAD REVIEWER COMMENTS: The verification testing is adequate and shows that the home monitor can receive data transmissions from the ICM for a projected range. The same deficiency written in the GLP Animal Testing section applies to the Wireless Range Verification Testing. It is copied below. Another deficiency will be sent to the sponsor regarding missing testing information. See below:

1. *You have provided wireless telemetry performance testing in both the GLP Animal Study and the Wireless Range Verification Testing in your submission. In your GLP Animal Study, results showed that device transmission success rate for all devices averaged 83% and CareLink transmission success rate for all monitors averaged 90%. In your Wireless Range Verification Testing, you demonstrated that data transmission had a success rate of 96%. It is unclear why there is a discrepancy between the success rates of these two verification activities. Please provide the following information:*
    a. *Define the success rate used to calculate percentages in both the GLP Animal Study and the Wireless Range Verification Testing;*
    The sponsor provided the success rate of (b)(4) Trade Secret/CCI *(in Amendment 1). This equates to 96% success. This information is acceptable.*
    b. *Define what data is being transmitted and points of transmission for each success rate calculated;*
    The sponsor provides the key data transmitted by the MyCareLink monitor. This is for informational purposes and is acceptable.
    c. *Justify why a success rate of 83% does not affect the safety or effectiveness of the subject devices, as compared to the 90% and 96% success rates.*
    The 83% success rate from the device to the MyCareLink monitor and the 90% success rate from the MyCareLink monitor to CareLink that was seen in the GLP study did not reflect the final wireless design configuration of the system. The testing described in the test report (b)(4) Trade Secret/CCI *) reflects the final system configuration. The testing in* (b)(4) Trade Secret/CCI *showed a 96% transmission success rate from the device to the MyCareLink monitor. The success rate from the MyCareLink monitor to CareLink was 100%. It should be noted that the lead reviewer for the ICM also sent a similar deficiency regarding the Wireless Transmission success rate. In the response to Mr. Ralston's deficiencies, the sponsor provided a more detailed description of the differences between the GLP-tested system and the final system configuration. Based on his review, he found these differences to be acceptable despite the significant difference in success rates between the GLP animal study wireless testing and the bench wireless testing. From my standpoint, a 96% data transmission success rate for the bench testing presented in the subject submission meets FDA's standards for transmission success rate and I have no further concerns.*

2. *You have included the* (b)(4) Trade Secret/CCI *in Attachment 12 of your submission. You have provided a brief summary of the results of this verification plan in the* (b)(4) Trade Secret/CCI *Verification Reports in Attachment 16 of the submission. However, you have not provided the completed test report that corresponds to the test plan. This is important to ensure that all tests were carried out and met the acceptance criteria. Please provide the completed test report for the Wireless Range Verification Plan.*

   The sponsor has provided the (b)(4) Trade Secret/CCI (b)(4) Trade Secret/CCI *in Attachment 2 of P890003/S285/A001. This shows the raw data of the wireless testing, results and conclusion. There are no concerns with this information and raw data/results are consistent with what was submitted in the original submission. This is sufficient.*

Labeling

The labeling for the Reveal LINQ system does not include information regarding the wireless telemetry. The following deficiency was sent to the sponsor in the November 2013 Major Deficiency Letter:

> *Labeling for medical devices and systems incorporating wireless technology should include a description of the wireless technology and information about how the system should be configured and operated with details such as the needed quality of service, operating distances and ranges, security requirements, and how to deal with risks and problems that may arise. Please add this information to the labeling of your device.*
>
> *REVIEWER COMMENTS: The sponsor has addressed this deficiency in Amendment 1. Provided are excerpts of the patient labeling which address the topics listed above. I am comfortable with the information provided to the patients and feel that the appropriate instructions for use are provided.*

Wireless Coexistence

The wireless distance telemetry feature operates in the 401-402 MHz portion of the MedRadio band which is used only by MetAids (i.e. weather balloons) or medical devices in most geographies. Coexistence in that band is controlled through the MedRadio (or equivalent MEDS) definition. Coexistence with MetAids is unlikely in a home environment due to the fact that MetAids transmitters are typically not stationary and will rapidly move away from any home. Interference of a MetAids system by a LINQ device is also mitigated by operating under 47 CFR Part 95 § 95.628(b)(2) which limits transmissions to a duty cycle of 0.1% per hour and effective isotropic radiated power to 250nW (-36 dBm).

> *LEAD REVIEWER COMMENTS: Because the telemetry feature operates in the 401-402 MHz MedRadio band, coexistence testing is not necessary. This is because this band is strictly used for medical device telemetry. Additionally, according to the protocol for this*

band, the device must check to see that the band is clear before transmitting data (inherent to the MedRadio band). I have no further concerns.

Security

Security of the wireless distance telemetry is provided through the use of (b)(4) Trade Secret/CCI (b)(4) Trade Secr . (b)(4) Trade Secret/CCI

LEAD REVIEWER COMMENTS: The encryption method used for this system is adequate. I have no further concerns.

GLP Animal Testing

A GLP Animal Study was run against study protocol (b)(4) Trade Secret/CCI . (b)(4) Trade Secret/CCI were tested with each animal having (b)(4) Trade Secret/CCI implanted on the same side of the animal. The objectives of the study were to:

1. To measure performance of the Reveal (LINQ) system with respect to the following:
   a. Wireless Telemetry Performance
      i. Frequency of successful wireless communication from Reveal LINQ devices to MyCareLink patient monitors
      ii. Frequency of successful wireless transmissions from MyCareLink patient monitors to the Medtronic CareLink network
   b. Detection of Arrhythmic Episodes
   c. Positive predictive value (true positives/(false positives + true positives) of the following episodes, as determined by review of acquired save-to-media:
      i. Bradycardia
      ii. Atrial Fibrillation (AF)
      iii. Atrial Tachycardia (AT)
      iv. Ventricular Tachycardia (VT)
      v. Fast Ventricular Tachycardia (FVT)
      vi. Pause
2. To verify performance of the Reveal LINQ insertion tool with respect to the following:
   a. Delivery of Reveal LINQ (b)(4) Trade Secret/CCI its intended implant location.
   b. Delivery of Reveal LINQ (b)(4) Trade Secret/CCI from patient
   c. Delivery of Reveal LINQ (b)(4) Trade Secret/CCI) below skin

Device transmission success rate for all devices averaged 83%. CareLink transmission success rate for all monitors averaged 90%.

LEAD REVIEWER COMMENTS: A veterinary reviewer was assigned a consult to review the animal testing information in this submission. In the first round of review, she recommended that the following deficiencies be sent to the sponsor. Her review comments for the deficiency responses in Amendment 1 are included under the deficiency.

1. *You have provided study results from GLP* (b)(4) Trade Secret/CCI *in your submission. Although these results appear, omissions in the preclinical final reports submitted prevent FDA from completing an assessment of your study. The following data are needed in order to substantiate statements and/or conclusions contained in your final study reports. Accordingly, please provide the following:*
    a. *Copies of raw data including:*
        i. *The individual animal health records, preferably in SOAP format;*
        ii. *Animal vendor invoices;*
        iii. *A report from the Attending Veterinarian describing the health, behavior, and attitude of the animals during the course of the study;*
        iv. *You believe* (b)(4) Trade Secret/CCI *You commented that* (b)(4) Trade Secret/CCI *therefore rotation of these two devices is the most likely cause for the detected pause episodes. Please provide copies* (b)(4) Trade Secret/CCI *that you referred to in explanation of the pause episodes. Copies of the two radiographs are necessary to verify your interpretation.*
    b. *A copy of the signed and* (b)(4) Trade Secret/CCI *protocol.*

Analysis of a i, ii, iii: The data was found in the respective attachments. The animal health records (Attachment 4) were complete although a few discrepancies were noted. For example, weight charts were not present in all animal files, but this is minor. The records provide documentation that supports the veterinary clinician report and the Final Study Report. The invoice records from the vendor indicate that (b)(4) Trade Secret/CCI *The report from the clinical veterinarian lacked substantive detail regarding daily health of the animals but did provide additional information regarding study data monitoring points and review of radiographs for evidence of device movement/dislodgement. The response was complete.*

Analysis of a iv: In (b)(4) Trade Secret/CCI

(b)(4) Trade Secret/CCI

. Rotation of the devices could explain the "pauses" detected by the device. FDA accepts the response.

Analysis of b: (b)(4) Trade Secret/CCI *protocol was found in Attachment 7, as indicated. The cover page contained electronic signature and dates of* (b)(4) Trade Secret/CCI *. The study design was identical to the GLP Study Protocol and* (b)(4) Trade Secret/CCI *authorized. FDA accepts the response.*

This deficiency is addressed in the Wireless Range Verification Testing in regards to the GLP animal study can be found on page 9 of this memorandum.

Human Factors

Medtronic conducted human factors testing to evaluate the usability of the Reveal LINQ system. During the development of the design, (b)(4) Trade Secret/CCI were conducted to improve the design and determine if progress was being made in meeting project usability goals. The sponsor has provided the general test methods used in the testing, usability goals measured, progress toward meeting the goals in formative testing, and summaries of each of the tests. In addition (b)(4) Trade Secret/CCI evaluations, (b)(4) Trade Secret/CCI .

(b)(4) Trade Secret/CCI The implant tools and procedure, device set-up user interface, device programming user interface, and remote monitoring user interface were tested with participants. Both full task and part task scenarios were used to evaluate product performance.

Detailed information about test protocols and results can be found in the (b)(4) Trade Secret/CCI P890003/S285 Attachment 38.

LEAD REVIEWER COMMENTS: A human factors reviewer was assigned a consult to review the human factors information included in the original submission. In the first round of review, she recommended that the following deficiency be sent to the sponsor in the November 2013 Major Deficiency Letter:

1. *You have provided a table of modifications made to the Reveal LINQ System in on pages 1-17 to 1-19 of your submission. It is unclear if all of these modifications were validated in the human factors validation testing you conducted (described in Attachment 38). This is important to determine if these modifications have been*

evaluated to meet user needs and promote usability of the device. Please provide the following information:

a. *Please clarify whether the tasks and use scenarios performed in that testing incorporated all of the modifications made to the system.*
b. *If use errors on tasks or use scenarios involving modifications made to the system could result in serious harm to the patient and were not included in the human factors validation testing you provided, please conduct additional tests to validate these tasks and use scenarios or provide rationale for omission of these tests. These tests would be necessary to assess whether the intended users could perform those tasks and use scenarios correctly, whether the implemented modifications were effective at reducing known use-related risks to acceptable levels and whether the modifications introduced any new risks.*

The reviewer has reviewed the sponsor's responses included in Amendment 1 for this deficiency. She finds the information provided to be acceptable. I agree with her assessment.

System Verification

System verification testing was performed to ensure that the Reveal LINQ system operates as intended. (b)(4) Trade Secret/CCI in Attachment 8 outlines testing requirements. After completion of the verification testing, the (b)(4) Trade Secret/CCI Attachment 16 was written.

LEAD REVIEWER COMMENTS: I believe the system has been fully verified based on the report in Attachment 16. Because this verification testing includes the entire system and not just the software listed above, I will defer to K132649 for the verification of the implantable cardiac monitor (currently under review by Luke Ralston). Four (4) anomalies were found during system verification testing regarding the programmer software. These anomalies were defined as acceptable by the sponsor and I agree with this assessment.

System Validation

Validation is intended to ensure that the system meets the needs of the user and the patient, and goes beyond the more technical verification, that the design output meets the design inputs. (b)(4) Trade Secret/CCI Attachment 10 provides detailed information about the strategy of the system validation activities for the Reveal LINQ project.

The System Validation Test Plan includes the strategy for (b)(4) Trade Secret/CCI . A minor anomaly was found but deemed to be acceptable. After completion of the validation, the (b)(4) Trade Secret/CCI Attachment 17 was finalized.

LEAD REVIEWER COMMENTS: Because this validation testing includes the entire system and not just the software listed above, I will defer to K132649 for the validation of the implantable cardiac monitor (currently under review). The validation test report in shows three (3) acceptable anomalies as a result of the testing. These anomalies are minor and I believe the sponsor was correct in determining that they are acceptable. Proper mitigations are in place.

Conclusion

I believe the sponsor has demonstrated safety and effectiveness for the modifications to the software that support the Reveal LINQ ICM. All deficiencies have been appropriately addressed. The consulting reviewers believe that this supplement should be approved based on their review of the GLP animal study and Human Factors information, respectively. As mentioned previously, coordination of the approval of this supplement and clearance of K132649 is necessary, as the ICM cannot function without the MyCareLink monitor. I recommend approval of this supplement based on the fact that the corresponding 510(k) will be cleared.