MEMORANDUM

From: Doris Terry IEDB
To: Files # P010031/S413, P980016/S451 and P890003/S295
Subject: Updates to Viva/Brava/Evera – Post Sterilization Test, Model SW016 and Manual Changes – Transparency Memo
Date: March 12, 2014
Office: DCD/ODE

The manufacturer, Medtronic, Inc., requested approval for changes in the final device configuration firmware, programmer application software, Model SW016, and the labeling manuals. An overview of the file and the recommendation which takes into account consulting reviews are included below.

<u>Overview of the File</u>

<u>Description of Changes</u>

The post sterilization test (PST) is performed at the Medtronic final device configuration facilities. The test consists of the following:

- Turn off the background flash memory scan to avoid interaction between the background scan function in conjunction with any firmware patch that may be installed on the device which may result in a Power on Reset (POR).

- Update the PST process to include a Cyclic Redundancy Check for all configuration files which allows for verification of test records and apply best practices for manufacturing file control.

- Update the excessive capacitor charge time parameters from ^(b)(4) Trade Secret/CC seconds to avoid incorrectly enabling the charge circuit maintenance when initially charging a device which has not warmed to room temperature.

- Update the VF number of intervals (NID) shipping parameters from 24/32 to 30/40 to reduce the incidence of unnecessary therapy delivered by the devices.

    Note: Data which described the VF NID and parameter functionality were submitted for our review in support of the NID update (Previous approval was granted for the requested VF NID).

Medtronic is also seeking to (b)(4) Trade Secret/CCI)(4) Trade Secret/CCI

(b)(4) Trade Secret/CCI update to Model SW016 for the Viva/Brava/Evera device will be designated as Model SW016 v8.1. The programmer application changes which will configure implanted devices include the following:

- Turn off the background memory scan at the next implanted device interrogation to avoid the interaction as noted above.

- Change the battery longevity estimation by ignoring the first voltage entry following a POR to avoid underestimating the battery longevity.

- Change the VF NID as noted above 24/32 to 30/40 (This issue was addressed in a Pre-IDE submission where we agreed to the 30/40 VF NID as a default setting).

- Add Chinese and Russian translations and miscellaneous SW016 updates to address legacy issues, (b)(4) Trade Secret/CCI system error during report generation, remote interrogate indication not obvious on Japanese language screen, Spanish language (b)(4) Trade Secret/CCI, fix stripchart annotation and inconsistent "V blanking post VP" value in TherapyGuide.

- Add functionality to allow Model SW016 application software (b)(4) Trade Secret/CCI (b)(4) Trade Secret/CCI

The labeling changes consist of updating the manuals to reflect: (1) the change in the VF NID; (2) the hyperbaric oxygen therapy (HBOT) to device specifications and device tested limits; and (3) the Diathermy language to clarify the use of therapeutic ultrasound and to be consistent with other Medtronic implanted devices.

Two of the changes above address (b)(4) Trade Secret/CCI: (1) unexpected interaction between flash memory scan functionality and firmware patches resulting in POR and POR in estimating longevity. (b)(4) Trade Secret/CCI

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Medtronic is also seeking to (b)(4) Trade Secret/CCI

System and Device Design Verification

Tests were performed to ensure that the design outputs met the design input requirement. System design validation reports were provided for review. The reports demonstrated that SW016 v8.0 and 8.1 met design input requirements under actual or simulated use conditions. The validation activities included bench testing on production units to validate that the system

conformed to the project-defined user need and intended uses under simulated use conditions. The results of the validation testing supported that the SW016 is validated for human use. According to the manufacturer, all testing was performed in accordance with (b)(4) Trade Secret/CCI (b)(4) Trade Secret/CCI System Validation Test Plan and (b)(4) Trade Secret/CCI System Design Validation Plan. Nine anomalies were found during verification/validation testing and were found to have been deemed acceptable and do not require communication via an errata sheet (The software validation testing and anomalies were also reviewed by the software consultant with no concerns).

Software Validation and Documentation

The Model SW016 Application Software is loaded on the marketed CareLink Model 2090 programmer or Model 29901 Encore programmer and is responsible for providing support for the Blackwell devices (Viva/Brava/Evera). The previously approved Application Software Model SW016v1.0.1 served as a baseline to create the Model SW016 v8.0 and v8.1.

Hazard analyses were performed and all identified hazard scenarios have been either mitigated or at an acceptable level of residual risk; there is no incremental risk of critical harm due to the changes as described. The manufacturer provided a detailed description of the architecture design of the SW016. Traceability analysis allowed each software requirement to be traced to individual tests in the verification test specification. The trace analysis was done and provided for our review. No concerns were identified.

Labeling

The labeling as presented adequately reflects the changes as noted above. No questions regarding the labeling information.

Consulting Reviews

The software reviewer reviewed the validation data of the software updates and concluded that all design and developmental specifications for the modifications noted above had been met. No concerns about the validation tests/results as presented.

The medical reviewer reviewed the request for the 30/40 VF NID setting. As previously reviewed in an earlier file, she had no concerns (Regarding the implanted devices receiving the VFNID default setting of 30/40, it was noted that it will only change the nominal value and does not reprogram the VFNID.

The reviewer of the data regarding the change in the battery longevity estimation by ignoring the first voltage entry following a POR to avoid underestimating the battery longevity, had questions

however, the questions were satisfactorily answered by the manufacturer. No additional concerns/questions remain

<u>Recommendation</u>

Approval recommended for the referenced bundled files.

Doris J. Terry -S