1) Exhibit parts-list/tuneup states "Additional info will be uploaded shortly"; please amend filing.

List has been uploaded.

2) Agent cover letter mentions "MICS" - for the record we note again that term is obsolete for FCC purposes.

Noted, agent letter will be revised in future applications.

3) User manual exhibit at hand ostensibly is for physician/clinical purposes.
Consistent with 2.1033(c)(3), please submit copy of the operating instructions to be furnished the user (i.e. implantee).

User manual is submitted with the Patient Therapy Manual device certification application which is the patient interface to the implant. Since this is system consisting of PTM, RTM, and Implant components there is no separate user manual provided other than that which is filed with the Patient Therapy Manual. The full document is approximately 20 Mb and is uploaded as individual files of about 5 Mb.

Manual has been uploaded.

4) This device ostensibly has receiver function/component that tunes around 402-405 MHz; which per 15.101(b) is subject to separate Verification equipment authorization [15.31(k), 2.911(b)].

Receiver compliance data is part of the test report that is uploaded as “Revised Test Report”. Further also to item 3), please amend filing to explain/show compliance with the 15.19(a)(1) [15.19(a)(5)] applicable requirement.

This device is implanted and the required administrative labels specified in Part 15 and Part 95 are on a separate sheet in the user manual. This statement was previously uploaded as an exhibit titled “Manual Label Information”. A sterile package label was also previously uploaded as required by the Part 95 rules.

5) For "Recharge and Proximal Antenna" indicated in the filing, please identify:
a) transmit and receive frequencies;

The recharge system operates at 40 kHz and is a one way link from the external RTM proximal antenna to the implant. There is also a one-way communications link from the Proximal Antenna to the implant at 175 kHz. When switching from recharge to communications, the proximal antenna coil is retuned to 175 kHz. The implant does not communicate to the RTM.

b) for (charger + implant) system, i.e. implant that operates with, or is marketed with, charger that requires an equipment authorization, what additional type of equipment authorization and/or FCC ID (associated equipment) is intended / applied for the charger.

The 175 kHz RTM link is being or will be certified under RTM FCC ID LF597755. It has been determined and verified by the FCC Lab that the recharge function is subject to verification as a Part 18 non-consumer device. Therefore the charging function does not carry an FCC ID related to its operation. However, the RTM unit ,which supports the recharge and communications at 175 kHz, will carry an FCC ID associated only with the 175 kHz communications function. That application has been awaiting a confirmation from the FCC that the recharge function is only subject to verification and will be filed shortly through a TCB.

6) EMC/radio report includes the following ambiguities and/or inapplicable indications.
a) pdf pg 7/47
"Testing Objective:
To meet the essential EMC and radio spectrum requirements according to Industry Canada standards."
b) pdf pg 1/47
"Report No. ... DRAFT"
c) pdf pg 2/47
"Certificate of Test
...
RSS-243:2010 ..."

Further to 2.1033(c)(14), please amend to explicitly show compliance for 2.1046 through 2.1057, AND 2.911(b) i.e. part 95 test data and information requirements.

[Incl: 2013 e-CFR 95.627(d), 95.627(e)(1), 95.627(g)(3), 95.633(e),
95.635(d)(1)(i), 95.635(d)(2), 95.635(d)(3), 95.635(d)(4),
95.639(f)(1) report EIRP data [95.627(g)(3)], 95.1209(b), 95.1209(c).

A revised final test report has been uploaded to the FCC file for the implant that corrects the errors listed in the original draft report. Also, a cross reference between the Part 95 technical requirements and the Part 2 general measurement requirements has been uploaded. This sheet includes a power calculation of 88.2 nW based on the new report from NWEMC. Please revise the Form 731 as needed.

As for 95.1209(b), this implant only operates in response to a transmission from a MedRadio programmer/control transmitter.
95.1209(c) does not apply to this implant.
Compliance with 95.635(d)(1)(i) is shown on pages 11-13 of the revised test report for emissions near the 402-405 MHz band and pages 34-36 for spurious emissions further outside the band of operation in the revised test report

7) f731 lists emission designator "58P1D"; if not in filing already please amend to explain/show how that is determined.

Correspondence reference #44087; Application reference #EA272123

The revised test report, corrected for errors shown above in items 6 and others, list an occupied bandwidth (emission bandwidth) of 64.6 kHz. Thus the emission designator will be 64k6G1D for digital phase modulation.
Please correct the Form 731 if needed.

8) RF exposure evaluation indicates antenna feedpoint power of -0.55 dBm = 1 mW.
For reference text from KDB pub 447498 D01 v05r01 is repeated below.
If not in exhibits already, please give details how antenna feed power is determined / measured.

The hybrid is designed to have a maximum output of 1 mW and has an actual measured output power lower than that level. The feed point power of -0.55 dBm is slightly less than 1 mW and is a measured value. Medtronic measures the output of each hybrid radio by matching it to a load that mimics the actual impedance of the human body the implant will see when implanted. The output from the load is measured and measures the power the hybrid will deliver to the antenna input. Since the antenna design is based a rod antenna it's feed point is the base end of the rod.