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October 26, 2011

Federal Communications Commission 7435 Oakland Mills Rd. Columbia, MD 21036

Re: Correspondence Reference Number: 40144; 8/4/2011

731 Conformation Number: EA439873

Y8L-MN0200

Subject: Response and clarification to Item 5 for updated SAR report.

- 5) The FCC will consider the FIT computational method for evaluation of RF exposure provided that the following are addressed:
- a.i) The general recommendations in Supplement C 01-01 for FDTD and the reporting requirements (Appendix B) are followed to validate the numerical codes used by the FIT simulation package used for the calculations. The FIT package developer should provide documentation, in the form of applicable computational standards protocols, or other acceptable requirements specific to the simulation package, demonstrating that the underlying numerical codes and algorithm implementations are accurate and acceptable for the SAR modeling required for this MedRadio device.

A detailed summary, including benchmark setup and results, should be included in the SAR report to verify code and:

- *Numerical accuracy:* Appendix 2.
- *Numerical dispersion*: Section 4, paragraph 3.
- *Absorbing boundary conditions:* Appendix 4.
- *Voxel resolution requirements:* Section 4.2
- *SAR averaging algorithm accuracy:* Appendix 2, 3.
- a.ii) The results of **at least two benchmarks** should be included; both simple and complex configurations for **free-space and multiple tissue dielectric media** should be considered and compared to established benchmark results. You may use the benchmark models specified in the latest draft of IEEE P1528.1 (May 2011) or equivalent models.
 - Free-space: Appendix 2.
 - Multiple tissue dielectrics: Appendix 6.
- a.iii) The SAR benchmark tests of a standard dipole source described in Annex D of IEEE Std 1597.2-2010 may be considered for the simple benchmark configuration case. Appendix 5.
- b.i) The numerical model of the test device must be verified against specific operating parameters of the actual device to confirm that it is an accurate representation for performing the SAR simulation. For example, S parameters and resonance frequency may be calculated from the model and the results compared against actual measured parameters.



Spinal Modulation 1135 O'Brien Dr. Menlo Park, CA 94025 Figures 7 and 8. http://www.spinalmodulation.com/ Direct: 650 543-6800 Fax: 650 327-2336

- b.ii) An explanation of any discrepancies between the modeled and measured results should be provided, along with the methodology used resolve the discrepancy. Section 5.2, paragraph 3, 4.
- b.iii) Methods such as scaling are generally preferred to modifying or adding components to the model, as that may result in a model that is no longer representative of the actual device. Also, the calculated field strength values at specific locations may be compared against measured values, if available. Since the computed SAR may be scaled to the device maximum output power level, reliable maximum conducted output measurement results, or an alternate means of accurately establishing output power, are necessary to support the SAR scaling.

Figure 7, point [1], is a 50 point in the circuit and power is measured at an Antenna-Test-Port connector with a system measurement uncertainty of +/- 0.5 dB.

c) A description of the procedures and locations used to determine sinusoidal steadystate conditions and source modeling considerations should be described in the SAR report.

Section 4, paragraph 3, figure 2.

- d) The recommendations in draft IEEE P1528.1 and general considerations in Supplement C 01-01 to estimate the computational uncertainty should be followed and addressed in the SAR report.

 Appendix 2, 3.
- e) Please provide further explanation of why the electrode leads, modeled at 20 times the actual radius, should have insignificant impact to the SAR distributions resulting from the antenna and other radiating structures of the test device. It should be noted that the numerical modeling considerations acceptable for this device may not apply to other circumstances without further consideration of the individual situations; for example, output power and SAR levels, applicability of simplifications to both device and tissue (phantom) models and other technical considerations.

The left SAR plot in Figure 11 clearly shows the exit point of the electrode leads are oneorder of magnitude below the peak SAR on the opposite side of the header. The continuation of the electrode leads show they are not in any appreciable field to affect the antenna radiation pattern or input impedance. The electrode leads in the actual and simulated implant device are electrically isolated from the implant 'can'.

Sincerely,

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