

August 16, 2011

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

Re: Correspondence Reference Number: 40106; 8/1/2011
731 Conformation Number: EA151513

Subject: Item 2; MPE document filed and application of 95.1221

The medical body-worn transmitter is subject to radio frequency radiation exposure evaluation, as appropriate (95.1221). Implant devices must contain a FDTD computational modeling report (95.1221); "Applications for equipment authorization of implant devices operating under this section must contain a finite difference time domain (FDTD) computational modeling report showing compliance with these provisions for fundamental emissions". The MN0100 is not an implant, and according to 95.1221 would not require FDTD computational modeling report. The MN0100 is a temporary external MedRadio used to evaluate the efficacy of a more permanent implant device according to 95.628(c) (4). While the device is not categorically excluded according to 1.1307 and 2.1093 radio frequency radiation exposure evaluation, the mitigating technical factors below provide an acceptable radio frequency radiation exposure evaluation. We would also claim that the device:

- Required to be worn outside the patients clothing (MN0100 Manual, Page 10, 1st paragraph).
- The antenna is 1cm away from the body; on the opposite side of the belt clip.
- Meets the "SUPPLEMENT C Edition 01-01 to OET BULLETIN 65 Edition 97-01" of < 50 mW; body contact to 2.5 cm away from the body. (Section 3, Page 16, footnote 14),
- Required to be less than 200 nW EIRP by 95.628(c) (4) (iii).

The MN0100 does comply with IEEE C95.1 1991 and 2005.

The MPE document filed for the MN0100 is not applicable.

Mitigating Technical Factors:

1. In order to meet the FCC 95.628(c) (4) (iii) requirement of less than 200 nW EIRP, the MN0100 conducted input power to the antenna must be < -21.5 dBm, or 7 uW. The antenna is physically unable to achieve 0.2 mW/cm² IEEE C95.1 1991 limit with a maximum 7 uW antenna input, or SAR Partial Body value of 1.6 W/kg averaged over 1 g of tissue volume in the shape of a cube; that equals approximately 1 cm³.
 - a. SAR limit of 1.6W/kg divided by 1000 = 1.6 mW/g.
 - b. Or in human body tissue; 1.6 mW/cm³ limit.
 - c. The density of human body tissue is similar to that of water; 1g ≈ 1 cm³.

Maximum SAR the MN0100 could possibly develop is 7uW/g if all the power conducted into the antenna was deposited into 1 g (1 cm³) of human tissue. The MN0100 is more than 100 times less than the permissible limit to IEEE C95.1 1991 or 2005 edition.

2. Limited communication. Estimated communication is twice per day for 1 minute each time. Duty cycle for that communication is much less than 25%, or 30 seconds per day.
 - a. Highest possible duty cycle is 50% during communication, typically 1 second burst, every few seconds, for approximately 2 minutes per day.
 - b. The worst case maximum duty cycle is 17% over a 6 minute period for a full firmware download that may occur once over the 3 year estimated lifespan of the device.

Sincerely,



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