ST. JUDE MEDICAL

Cardiac Rhythm
Management Division
15900 Valley View Court
Sylmar, CA 91342
800 777-2237
818 362-6822
818 364-5814 Fax

May 2, 2007

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

Re: Application for Grant Certification for FCC ID RIASJMRF

Dear Mr. Tim Harrington:

In response to your questions, we offer the following responses:

FCC Question:

6) cont.

if established, please provide intended FCC ID(s) for programmer/control transmitter

SJM Response:

The FCC ID will be RIASJMRFANT.

FCC Question:

9) As amd. to op. desc., if not in filing already please describe device features to prevent falsely enabling the programming of the implanted device by unintended 2.4 GHz signals.

Also, please describe how would situation be addressed in case of urgency where a doctor is trying to reprogram the device and can't get past the interlock because of a nearby high-strength 2.45 GHz signal.

SJM response:

As amendment to chapter 5 of the Operational description document:

The 2.4 GHz wakeup protocol has a two level protection guard to prevent unintentional communication access. At the first physical level a Manchester code scheme is used with bit level error identification. A complete 2.4 GHz wakeup message consists of 44

Manchester coded bits plus 8 special coded bits, which all must be received faultless in a sequence to be accepted as an error free message. The next logical protection level of the message is a 36 bit identification number, 8 bits for company ID and 24 bits for each individual implant ID. This code points out a specific implant. It shall be noted that programming of the device is not possible over the 2.4 GHz radio, since it is only used for initial communication setup, whereas the MICS bidirectional link with multi level protocol protection is used for the actual parameter access.

As amendment to the work flow described in chapter 5 of the Operational description document:

The RF system is secondary to the primary inductive telemetry system. In the normal clinical situation the implant is always first accessed by placing the inductive telemetry head over the implant to select and initiate a MICS communication link. The 2.4 GHz signaling system is a secondary wakeup system which can always be overridden by the inductive telemetry system, not only for initialization but also for the complete communication that excludes both the 2.4 GHz wakeup as well as the MICS link for all urgent device programming. The system will thus not be interlocked by any external 400 MHz or 2.4 GHz systems in any clinical situations.

FCC Question:

10) Please submit reference [2] listed in SAR report, with revised confidentiality-request letter if needed if there is copyright matter

SJM Response:

Copy of Ref 2 from the SAR reports –

S. Gutschling, H. Kruger, T. Welland: Modeling Dispersive Media Using the Finite Integration Technique. Proceedings of the 14th Annual Review of Progress in Applied computational Electromagnetics (ACES 1998), Vol 2 March 1998 pp 832-837

SJM response:

File has been uploaded separately.

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FCC Question:

11) please provide details of algorithm used to calculate 1-g average SAR, i.e., in terms of methods described in, e.g., IEEE P1529/D0.0 clause 8, IEEE P1528.1/D1.0 sec 5.1.

SJM response:

Please refer to clause 4.5 of the SAR reports. The averaging is conformal to IEEE C95.3.
As a further amendment to section 4.5:
CST Microwave Studio is using the Finite Integration Technique (FIT) that in time domain is a conformal FDTD method as described in section 2 of IEEE P1528.1/D1.0
The 1-g average SAR calculation works as follows:

1) Compute the losses in a cell:
Loss_x = 0.125 (sigma_1x |E_1x|^2 + ... + sigma_4x |E_4x|^2)
Loss_cell = Loss_x + Loss_y + Loss_z

2) Compute the mass of each cell (conformal integration):
Mass_cell = dx dy dz rho_cell

3) Find an averaging cube with a mass of 1 g (iteratively) and integrate the losses in this cube.

The described averaging procedure is therefore a 12 component averaging such as described in IEEE P1528.1/D1.0 sec 5.1.

If there are any questions, please feel free to contact me at 818-493-2629.

Sincerely,

Deanna Hughes
Regulatory Affairs
St. Jude Medical