IMTHERA

Date (23-Feb-2016)

TUV SUD BABT TCB/FCB
Octagon House,
Segensworth Road,
Fareham,
Hampshire,
PO15 5RL

Dear Sir or Madam,

We, *ImThera Medical, Inc., 12555 High Bluff Drive, Suit 310, San Diego, California 92130 USA,* hereby declare that the aura6000 Implantable Pulse Generator (ID: 2AGS5-IPG) complies with the requirements of Part 95 Subpart E §95.627(a)(1) to (4) as detailed below:

(a) Frequency monitoring. Except as provided in (b) of this section, all MedRadio programmer/control transmitters operating in the 401- 406 MHz band must operate under the control of a monitoring system that incorporates a mechanism for monitoring the channel or channels that the MedRadio system devices intend to occupy. The monitoring system antenna shall be the antenna normally used by the programmer/control transmitter for a communications session. Before the monitoring system of a MedRadio programmer/control transmitter initiates a MedRadio communications session, the following access criteria must be met:

(1) The monitoring system bandwidth measured at its 20 dB down points must be equal to or greater than the emission bandwidth of the intended transmission. We comply with this requirement by having the Remote Control and Charger (RCC, Master in this paired MedRadio telemetry system, the IPG being the Slave device) set its center frequency control registers to each of the 17 MedRadio Channel Frequencies in turn (401.01MHz, 401.31MHz, and every 300kHz higher through 405.85MHz), and its bandwidth control registers to 100kHz.

(2) Within 5 seconds prior to initiating a communications session, circuitry associated with a MedRadio programmer/control transmitter must monitor the channel or channels the system devices intend to occupy for a minimum of 10 milliseconds per channel. We comply with this requirement by having the Remote Control and Charger (RCC, Master in this paired MedRadio telemetry system, the IPG being the Slave device), set its center frequency control register to the first channel of the MedRadio Channel Frequencies, 401.01MHz. The RCC monitors this frequency for a minimum of 10ms and records the peak value of the received signal strength as measured by the transceiver (CC1101) RSSI register. The RCC then sets its center frequency to the next MedRadio Channel, 300kHz higher than the last frequency at 401.31MHz, and repeats this process until all 17 channels have been monitored.

(3) Based on use of an isotropic monitoring system antenna, the monitoring threshold power level must not be more than 10logB(Hz) −150 (dBm/Hz) + G(dBi), where B is the emission bandwidth of the MedRadio communications session transmitter having the widest emission and G is the MedRadio programmer/control transmitter monitoring system antenna gain relative to an isotropic antenna. For purposes of showing compliance with the above provision, the above calculated threshold power level must be increased or decreased by an amount equal to the monitoring system antenna gain above or below the gain of an isotropic antenna, respectively. We comply with this requirement by having the IPG and RCC set their power levels via control registers in the telemetry transceiver (CC1101) to values determined by tested performance by TUV to be compliant with this regulation.

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(4) If no signal in a MedRadio channel above the monitoring threshold power level is detected, the MedRadio programmer/control transmitter may initiate a MedRadio-communications session involving transmissions to and from a medical implant or medical body-worn device on that channel. The MedRadio communications session may continue as long as any silent period between consecutive data transmission bursts does not exceed 5 seconds. If a channel meeting the criteria in paragraph (a)(3) of this section is unavailable, MedRadio transmitters that are capable of operating on multiple channels may transmit on the alternate channel accessible by the device with the lowest monitored ambient power level. Except as provided in paragraph (b) of this section, MedRadio transmitters that operate on a single channel and thus do not have the capability of operating on alternate channels may not transmit unless no signal on the single channel of operation exceeds the monitoring threshold power level. We comply with this requirement by monitoring the MedRadio Band as described above, analyzing the RSSI data for the 17 MedRadio Channels, and the first channel in the MedRadio band that meets the requirements for Clear Channel status is selected and the RCC instructs the IPG to continue communication on this new channel.

Sincerely,

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