April 6, 2012

Federal Communications Commission Office of Engineering and Technology 7435 Oakland Mills Road Columbia, Maryland 21046

Dear Sir or Madam:

Please find our responses to your communication received on April 2 and 3, 2012: Correspondence Reference Number: 41507

- 1) We note mention in cover letter "incorporate an integrated low power inductively coupled telemetry coil, operating at 57 KHz"; and we note mention in user manual of telemetry wand Model 6577.
- a) FYI for FCC equipment authorization purposes, at minimum a telemetry or charging wand portion of an implant transmitter and program/control transmitter pair is requested to address the provisions of OET Lab. KDB pub. 680106.

Response: The KDB publication 680106 would not apply to the devices subject to equipment authorization because the inductive coupling between the model 3120 programmer (previously authorized under FCC ID: ESCCRM312005) and the implant is for telemetry purposes only; no power transfer or inductive charging function is incorporated in this system. The same is true for communication with the patient home monitoring device (previously authorized under FCC ID: ESCCRM647608).

b) Please provide FCC ID(s) of other device(s) subject to equipment authorization that operate together in a session with this implant transmitter as part of the telemetry system.

Response: The implant transmitter is used together in a session with either an external programmer device (FCC ID: ESCCRM312005), or a patient home monitoring device (FCC ID: ESCCRM647608)



2) If not in the filing already, per 2.925(f), please submit justification for not having permanently affixed nameplate with FCC ID number on the transmitter enclosure.

<u>Response:</u> Per 2.925(f) an alternate method of identification is requested because the devices subject to authorization are small in size and implanted inside the human body. Therefore, affixing the nameplate/FCC ID on the device itself would not be practical or feasible. Alternatively, the FCC ID has been included in the following product literature accompanying the device: System Guide, Physician's Technical Manual, and outer Box Label.

- 3) Cover letter and emc/radio report mention -1.25 dBm (radiated) output power.
- a) if not in filing already, please give details how that -1.25 dBm level was determined, and
- b) please give details about design or nominal or measured RF power fed to the antenna port.

Response: The nominal measured power at the RF antenna feed port is +1 dBm. The devices subject to authorization use a permanently attached/integrated antenna, which has a nominal antenna gain specified in part b) of the *Antenna Information.pdf* confidential exhibit. Because of this negative antenna gain, and other signal path losses, the devices have an output power less than -1.25 dBm (0.75 mW).

The question below was received the day following the initial communication and amends the referenced Correspondence:

4) The following listing is adapted from the cover letter in this filing dated 2/2/12.

INGENIOTM: K172, K173, K174, K175, K176, K177, ADVANTIOTM: K062, K063, K064, K065, K066, K067 VITALIOTM: K272, K273, K274, K275, K276, K277

INTUATM: V272, V273 INVIVETM: V172, VI73 FORMIOTM: K278, K279

a) Unless already in this filing, please submit case / enclosure length, width, thickness dimensional info for all versions intended under this FCC ID.

Response: Please see the confidential design schematics attached with this response. Device size varies based on inclusion of either a standard life (smaller) or extended life (larger) battery. Also, header block size is determined by the number of cardiac leads accommodated by the device. See the response to question 4(b) for additional details regarding the header block.

b) As part of this packaging info, please also identify the "header" (connector / terminal block number of leads) variations for each.

Response: Please see the confidential design schematics attached with this response. The header block is the upper portion of the device. The number of leads is identified by the port map on the device. For example, each "IS-1" label on the device indicates a lead. A device with "IS-1" labeled next to a port map containing "RA" (right atrium) and "RV" (right ventricle) accommodates two leads.

c) Please identify which if any have 916 MHz antenna variations vs. what is already shown in the internal photos herein, and what the variations are.

Response: There are no variations in antenna design. All devices subject to authorization incorporate the same antenna specification and routing, as shown in the internal photos and schematics.

Sincerely,

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