May 20, 2008

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

Dear Sir or Madam:

Please find the enclosed responses to the questions asked in Correspondence Reference Number 34865.

1) If not in filing already, please provide summary descriptions of differences between various "COGNIS" and "TELIGEN" models as listed in cover letter

Response: All of the COGNIS 100-D and TELIGEN 100 implantable devices have identical inductive and RF telemetry hardware with specific model numbers corresponding to differences in therapy features. The TELIGEN 100 device family is an Implantable Cardioverter Defibrillator (ICD) and is designed to treat sudden cardiac death. The COGNIS 100-D device family is a Cardiac Resynchronization Therapy Defibrillator (CRT-D) and is designed to treat sudden cardiac death as well as congestive heart failure.

2) If not in filing already, please address compliance with 15.31(e)

Response: The COGNIS 100-D and TELIGEN 100 devices are battery operated. Devices used for testing included a new battery, as required by 15.31(e).

4) Form-731 at item 14(c) [composite / associated device] mentions fccid ESCCRM312005 – please confirm whether that fccid is correct and explain how it operates with fccid ESCCRMN11906

Response: ESCCRM312005 is the correct FCC ID number for the composite/associated device which is called the Model 3120 Programmer/Recorder/Monitor (PRM). The 3120 PRM is a portable, non-implanted, interface system used in a clinical setting to begin and continue a communication session with all Boston Scientific implantable devices, including the COGNIS

100-D and TELIGEN 100 products which will operate under FCC ID ESCCRMN11906. Additionally, the 3120 PRM is used to:

- interrogate the implantable device
- program therapy parameters
- display, record, and store patient data

5) Related to 2.1033(b)(5), please provide info about inductive telemetry circuit, and if not in filing already also details for how it operates with and/or activates 916 MHz function

Response: We have included the block diagram and schematic diagram for the inductive telemetry circuit as separate attachments as part of this response. The inductive telemetry circuit does not allow for tuning or use of intermediate frequencies.

In the typical case, the physician places an inductive coil, called a "wand", on the patient's chest, to establish an inductive link between the wand and the implanted device. The wand, which is connected to the external 3120 PRM, must be within inches of the implant to receive its extremely low level transmission. The programmer initially executes a "handshake" protocol with the implanted device to establish a telemetry session, and then shifts to 916.5 MHz transmissions to continue the session after the inductive "handshake". The COGNIS 100-D and TELIGEN 100 devices rely on 916.5 MHz transmissions for its primary means of communication, and it will use inductive telemetry only for the purpose of initiating the "handshake" between the implanted device and the external 3120 PRM and as a backup means of communication.

6) 15.19 (a)(5) requires FCCID on device – please revise filing where appropriate

Response: Per 2.925(f), an alternate method of identification is appropriate since the COGNIS 100-D and TELIGEN 100 devices are implanted within the body. Therefore, the FCC ID is placed on the System Guide, Box Label, and Physicians Technical Manual.

Sincerely,

Rachit Jain
Electrical Engineer
Engineering Compliance
Tel: (651) 582-7556
Fax: (651) 582-2830
Email: richie.jain@bsci.com