DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Boston Scientific Confidential

MAY - 8 2008

[redacted]
Principal Regulatory Affairs Specialist
Guidant Corporation
A Boston Scientific Company
4100 Hamline Avenue North
St. Paul, MN 55112

Re: P960040/S155
TELIGEN Implantable Cardioverter Defibrillator Models E102 and E110, the Application Software Model 2868, Rev. 1.01 and Model 6828 Torque Wrench

P010012/S165
COGNIS Cardiac Resynchronization Therapy Defibrillator (CRT-D) Models N118 and N119, the Application Software Model 2868, Rev. 1.01 and Model 6828 Torque Wrench

Filed: December 7, 2007
Amended: April 4, 2008

Dear [redacted]

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your premarket approval application (PMA) supplement, which requested approval for the TELIGEN Implantable Cardioverter Defibrillator Models E102 and E110, the COGNIS Cardiac Resynchronization Therapy Defibrillator (CRT-D) Models N118 and N119, Application Software Model 2868, Rev. 1.01 and the Model 6828 Torque Wrench. The device, as modified, will be marketed under the trade name TELIGEN Implantable Cardioverter Defibrillator Models E102 and E110, the COGNIS Cardiac Resynchronization Therapy Defibrillator (CRT-D) Models N118 and N119, Application Software Model 2868, Rev. 1.01 and the Model 6828 Torque Wrench. The COGNIS CRT-D devices are indicated for patients with moderate-to-severe heart failure (NYHA III/IV) who remain symptomatic despite stable, optimal failure drug therapy, and have left ventricular (LV) dysfunction (ejection fraction $\leq$35%) and QRS duration $\geq$120 ms. The TELIGEN devices are intended to provide ventricular antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Based upon the information submitted, the PMA supplement is approved. You may begin commercial distribution of the device as modified by your PMA supplement in accordance with the conditions described below and in the "Conditions of Approval for Implantable Defibrillators and Programmers" (enclosed).

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

Expiration dating for the TELIGEN and COGNIS has been established and approved at 12 months.

CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.

Failure to comply with any postapproval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that as soon as possible and before commercial distribution of your device you must submit an amendment to this PMA with copies of all approved labeling in final form. The labeling will not routinely be reviewed by FDA staff when PMA supplement applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have questions concerning this approval order, please contact [redacted] at [redacted]

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure