DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 1999

Mr. Brian Novak
Senior Regulatory Affairs Associate
Guidant Corporation
Cardiac Pacemakers (CPI)
4100 Hamline Avenue North
St. Paul, MN 55112-5798

Re: D970003
Guidant PULSAR™ Models 470, 970, 972, 1172, 1272
Pulse Generators,
Guidant PULSAR™/PULSAR Max™ Models 1170, 1171, 1270
Pulse Generators
Guidant CONSULT™ (Model 2890) Software
Filed: March 5, 1999
Amended: March 25 and June 2, 1999

Dear Mr. Novak:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your notice of completion (NOC) for your product development protocol (PDP) for the:

Guidant PULSAR™ Models 470, 970, 972, 1172, 1272 Pulse Generators,
Guidant PULSAR Max™ Models 1170, 1171, 1270 Pulse Generators, and
Guidant CONSULT™ (Model 2890) Software.

Guidant PULSAR™/PULSAR Max™ series pacemakers are indicated for the following:

- Symptomatic paroxysmal or permanent second or third-degree AV block
- Symptomatic bilateral bundle branch block
- Symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders (eg, sinus bradycardia, sinus arrest, sinoatrial [SA] block)
- Bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias
- Neurovascular (vasovagal) syndromes or hypersensitive carotid sinus syndromes

Adaptive-rate pacing is indicated for patients who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity.

The PULSAR™/PULSAR Max™ series pacemakers' dual chamber and atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of the following:

- Conduction disorders that require restoration of AV synchrony, including varying degrees of AV block
- VVI intolerance (e.g., pacemaker syndrome) in the presence of persistent sinus rhythm
- Low cardiac output or congestive heart failure secondary to bradycardia

We are pleased to inform you that the PDP is declared completed subject to the conditions described below and in the "Conditions of Approval for Cardiac Pacemakers and Programmers" (enclosed). You may begin commercial distribution of the device upon receipt of this letter. A device with a completed PDP is considered to have an approved premarket approval application (PMA) in accordance with section 515(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) and is subject to the requirements described under 21 CFR 814.

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 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) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

In response to observations of short circuit/rapid battery depletion and issues relating to minute ventilation calibration, interim solutions have been put into place and are acceptable. The following conditions of approval are intended to ensure permanent solutions, and must be complied with:

1. **Short Circuit/Rapid Battery Depletion Issue** - Within 180 days of the date of this letter, you must submit a PDP supplement to provide a permanent fix for the rapid battery depletion issue (caused by inadvertent contact between stacked integrated circuits) to FDA, or provide some other mutually agreeable solution.

Until approval for the permanent fix (or other mutually agreeable solution) noted above is granted, you must submit monthly reports on any failures or events associated with or attributable to rapid battery depletion.

2. **Minute Ventilation Calibration Warning** - Within 90 days of the date of this letter, you must submit a PDP supplement to eliminate the MV auto-initialization feature. MV calibration will be limited to the manual 4-ON method only. Physician's manual and other labeling must be modified as needed to provide the new configuration information. The Model 2890 software application must be modified to have the following Minute Ventilation (MV) Calibration Warning appear as a "pop-up" message before the 4-ON calibration screen is entered:

   ATTENTION: Sustained High Rate Pacing can occur. If this is a concern consider programming a reduced MSR or programming MV to passive. MV sensor performance should be evaluated at all follow-up visits until implant stabilization has occurred (see System Guide, Chapter 6- Therapy, " Minute Ventilation").

Expiration dating for this device has been established and approved at one year. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(8). We remind you that any loss of battery longevity as a result of increased shelf life must be clearly reflected in the labeling.

The change matrix entitled " PDP Change Proposal," an amendment to your PDP received February 26, 1998, may be used for guidance for the purpose of deciding when changes require reporting via progress report, or submission of a supplement under 21 CFR 814.39. You are reminded that a supplement to the PDP must be submitted to, and approved by FDA prior to implementation of any substantive changes.

CDRH will notify the public of its decision to approve your NOC by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061,

Rockville, MD 20852. The written request should include the PDP number or docket number.
Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Failure to comply with the conditions of approval invalidates this approval order. 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 PDP submission with copies of all approved labeling in final printed form. As part of our reengineering effort, the Office of Device Evaluation is piloting a new process for review of final printed labeling. The labeling will not routinely be reviewed by FDA staff when PDP 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. Please see the CDRH Pilot for Review of Final Printed Labeling document at http://www.fda.gov/cdrh/pmat/pilotpmat.html for further details.

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

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

Under section 519(e) of the act (as amended by the Safe Medical Devices Act in 1990), manufacturers of certain devices must track their products to the final user or patient so that devices can be located quickly if serious problems are occurring with the products. The tracking requirements apply to (1) permanent implants the failure of which would be reasonably likely to have serious adverse health consequences; (2) life sustaining or life supporting devices that are used outside of device user facilities the failure of which would be reasonably likely to have serious adverse health consequences; and (3) other devices that FDA has designated as requiring tracking. Under section 519(e), FDA believes that your device is a device that is

subject to tracking because it is a permanent implant whose failure would be reasonably likely to have serious adverse consequences. FDA has designated your device for tracking.

FDA's tracking regulations, published in the FEDERAL REGISTER on August 16, 1993, appear at 21 CFR Part 821. These regulations set out what you must do to track a device. In addition, the regulations list example permanent implant and life sustaining or life supporting devices that FDA believes must be tracked at 21 CFR 821.20(b) and the devices that FDA has designated for tracking at 21 CFR 821.20(c). FDA's rationale for identifying these devices is set out in the FEDERAL REGISTER (57 FR 10705-10709 (March 27, 1991), 57 FR 22973-22975 (May 29, 1992), and 58 FR 43451-43455 (August 16, 1993)).

If you have questions concerning this approval order, please contact Marian Kroen at (301) 443-8517.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure