Exhibit C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 4 2000

RECEIVED

[redacted]

CPI RECU

Ms. Laura L. Shepler
Senior Regulatory Affairs Associate
Guidant Corporation
Cardiac Rhythm Management
4100 Hamline Avenue North
St. Paul, MN 55112-5798

Re: P960040/S15
VENTAK® PRIZM™ 2 DR/VR AICD™ System and Model 2844, Version 3.1 Software
Filed: June 8, 2000

Dear Ms. Shepler:

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 qualified for review under the Real-Time Review Program. We have reviewed your application at a teleconference on July 27, 2000.

Your supplement requested approval for the Pulse Generator Models 1860 and 1861, Pulse Generator Software Version 1.3, and Program/ Recorder/Monitor Software Model 2844, Version 3.1. Based upon the information submitted, the PMA supplement is approved 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 as modified by your PMA supplement upon receipt of this letter.

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 that 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.

Failure to comply with the conditions of approval as attached 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 PMA supplement 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 PMA 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 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 Boulevard
Rockville, Maryland 20850

We are interested in continuing to improve the Real-Time PMA Program. If you have any suggestions for how we can modify it, please send a facsimile to Bonnie Markovitz at (301) 827-2930 or an electronic message to her at BAM@CDRH.FDA.GOV at CDRH.

If you have questions concerning this approval order, please contact Fred Lacy at (301) 443-8609 ext. 170.

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure