

May 30, 1997

Docket Number 95S-0158
Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., Rm. 1-23
Rockville, MD 20857

97
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PM 2:04

RE: **IDE Number G960214/S6**
CardioLogic VEST-CPR[®] System
IRB Approval of Clinical Investigation - Presbyterian Hospital

Dear Sir/Madam:

In accordance with 21 CFR 812.42, we are enclosing a copy of a letter from the Institutional Review Board (IRB) for the Presbyterian Hospital of Charlotte, NC, approving a clinical trial at that facility under IDE #G960214.

If there are any questions concerning this matter, please contact me at 410/691-5200, ext.45.

Sincerely,



Timothy R. Placek
Director of Regulatory Affairs
and Quality Assurance
Official Correspondent

95S-0158

SUP9

CARDIOLOGIC SYSTEMS, INC.

**IDE Number G960214
Supplement Number 6
May 30, 1997**

VOLUME 1

**SPONSORED BY:
CARDIOLOGIC SYSTEM, INC.
7455-T NEW RIDGE ROAD
HANOVER, MARYLAND, USA 21076-3143**





Presbyterian Healthcare System

Institute for Research and Technology
200 Hawthorne Lane
Post Office Box 33549
Charlotte, NC 28233-3549
(704) 384-5369 FAX (704) 384-5638
<http://www.presbyterian.org>

May 16, 1997

Diane Whisnant
Belk Heart Center
200 Hawthorne Lane
Charlotte, NC 28233

Investigator: Dr. Mark Kremers

RE: IRB # 97009

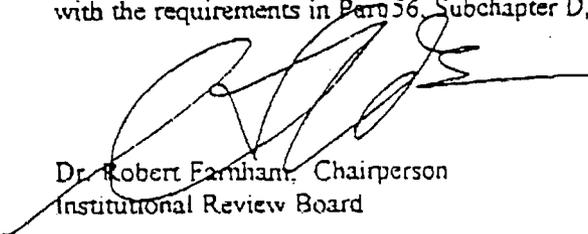
This is to confirm for your records that the Institutional Review Board (IRB) met on May 15, 1997 and voted approval on the protocol and informed consent for the entitled:

Multicenter Vest CPR Clinical Trial, Phase II

A copy of this protocol and consent form are on file. Any changes must be submitted to the IRB for review. Any unexpected or significant adverse effects should be reported immediately.

This approval is for six months or until termination of the study, whichever is less. Application for renewal should be made by November 1, 1997.

Minutes of this meeting are on file in Administration. The Institutional Review Board is in compliance with the requirements in Part 56, Subchapter D, Part 312 of 21 Code of Federal Regulations.



Dr. Robert Farnham, Chairperson
Institutional Review Board

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