



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

SEP 20 1988

Food and Drug Administration  
8757 Georgia Avenue  
Silver Spring MD 20910

Mr. Glenn A. Williams, Jr.  
President  
General Cardiac Technology, Inc.  
795 Carmel Avenue, Suite 3  
Sunnyvale, California 94086

Re: K882592  
Heart Hugger Sternum Support Harness  
Dated: June 21, 1988  
Received: June 23, 1988  
Regulatory Class: I

Dear Mr. Williams:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Pre-market Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Halyna P. Breslawec, Ph.D.  
Director  
Division of Gastroenterology-Urology  
and General Use Devices (HFZ-420)  
Office of Device Evaluation  
Center for Devices and  
Radiological Health