DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
SILVER SPRING, MARYLAND 20910

DEC 4 1978

Cal Bowman, J.D.
Director of Regulatory Affairs/
Quality Assurance
Shiley Incorporated
17600 Gillette Avenue
Irvine, CA 92714

Ref: K781990 - Shiley Cardiac
Insulation Pad

Dear Dr. Bowman:

Your Section 510(k) notification of intent to market the above device has been reviewed and we have determined the device to be substantially equivalent to one marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments of 1976. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act until such time as your device or the type of device to which it is substantially equivalent has been classified under Section 513. At that time your device would be subject to additional controls if it is classified into either class II (Standards) or class III (Premarket Approval).

General controls presently relate to annual registration and misbranding and adulteration provisions. In the near future, the present general controls will be supplemented by additional regulations relating to current good manufacturing practices, records and reports, and others.

All regulations and information on meetings of the device classification panels, their recommendations, and the final decisions of the Agency will be published in the FEDERAL REGISTER as proposals. You should peruse this publication so that you can convey your views to the Agency if you so desire, and so that you can promptly comply with any additional requirements subsequently imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Office of the Hearing Clerk, FDA, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter should not be construed as approval of your device or its labeling. If you desire comment as to the status of the labeling for your device or any additional information pertaining to your responsibilities under the law, please contact the Division of Compliance Operations, Bureau of Medical Devices, 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

David M. Link

David M. Link, Director
Bureau of Medical Devices

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