October 17, 2022

Gamma Enterprises, Inc.
Peter C. Fu
4221 Richmond Rd., N.W.
Walker, Michigan 49534

Re: K770082
Trade/Device Name: Salonmay Bustline Increaser
Regulation Number: 21 CFR 890.5660
Regulation Name: Therapeutic Massager
Regulatory Class: Class I
Product Code: MWZ

Dear Peter C. Fu:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 16, 1977. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under regulation number 890.5660.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact David Krause, OHT4: Office of Surgical and Infection Control Devices, 301-796-6970, David.Krause@fda.hhs.gov.

Sincerely,

David Krause -S

David Krause, Ph.D.
Deputy Office Director
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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

MAR 16 1977

Peter C. Fu
Gamma International Co., Ltd.
P.O. Box 3325
Culver City, California 90230

Ref: K770082
Salonmay Bustline Increaser

Dear Mr. Fu:

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, MD 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, Bureau of Medical Devices and Diagnostic Products, 8757 Georgia Avenue, Silver Spring, MD 20910.

Sincerely yours,

David M. Link

David M. Link, Director
Bureau of Medical Devices
and Diagnostic Products

FORM FLH 2973 (2/77)