



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

November 29, 1999

Telephone: 425-486-8788
FAX: 425-483-4996

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-21

Ms. JoAnn E. Rovig
President and Chief Executive Officer
Legacy Systems, Inc.
1800 NW Market Street, Suite 207
Seattle, Washington 98107-5229

WARNING LETTER

Dear Ms. Rovig:

On September 22 and 28, 1999, Investigator Kerri E. Butler collected information that revealed a serious regulatory problem involving the directional flow compressible limb sleeves manufactured by your firm. The specific products are:

1. Arm Units (M100AE, M100AG, M100AH, M100CG)
2. Glove Unit, GLOV
3. Leg Units (M200AE, M200AG)
4. Spiral Wrap (SP-6, SP-8)
5. Pressure Pads (PP-7, PP-10)
6. Breast Units (BR-1, BR-2, BR-3)
7. Thoracic Units (TH-U, TH-B)
8. Female Genital Pack, GP-F
9. Treatment Table Pad, TP2820

The Federal Food, Drug, and Cosmetic Act (Act), a United States Federal law, considers these directional flow compressible limb sleeves to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires manufacturers of medical devices to obtain marketing clearance for their products from the Food and Drug Administration before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that you obtained marketing clearance before you began offering your products for sale. The kind of information you need to submit in order to

JoAnn E. Rovig, President & CEO
Legacy Systems, Inc.
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obtain this clearance is described in the enclosed materials. The FDA will evaluate this information and decide whether your products may be legally marketed.

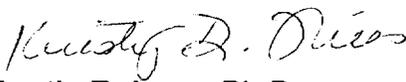
Marketing your products is a violation of the law until you have clearance from FDA. The products are adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your products are adulterated under the Act because you did not obtain premarket approval based on information developed by you that shows your devices are safe and effective. Your products are misbranded under the Act because you did not submit information that shows your devices are substantially equivalent to other devices that are legally marketed.

This is a serious violation of the law and may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the products, or assessing civil money penalties. Other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Thomas S. Piekarski, Compliance Officer, at the above mailing address.

There are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance for your devices and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at <http://www.fda.gov>.

Sincerely yours,


Austin R. Long, Ph.D.
Acting District Director

Enclosure:
Premarket Notification