



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

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HFI-35*

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Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(617)279-1675 FAX: (617)279-1742

WARNING LETTER

October 27, 1997

NWE-03-98W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Donald A. Seavey
Titan Manufacturing, Inc.
6 Jamie Lane
Phoenixville, PA 19460

Dear Mr. Seavey:

We are writing to you because during an inspection of your firm located in Holbrook, Massachusetts on September 4, 9, and 11, 1997, an investigator from the Food and Drug Administration (FDA) collected information that revealed serious regulatory problems involving the product known as "Bipolar Forceps" which is made and marketed by your firm.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), this product is considered to be a medical device because it is used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices obtain marketing clearance for their products from FDA 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 product for sale. The kind of information you need to submit in order to obtain this clearance is described in the enclosed materials. The FDA will evaluate this information and decide whether your product may be legally marketed.

Because you do not have marketing clearance from FDA, marketing your product is a violation of the law. In legal terms, the product is adulterated under Section 501(f)(1)(B) and is misbranded under Section 502(o) of the Act. Your product is adulterated under the Act because you did not

obtain premarket approval based on information developed by you that shows your device is safe and effective. Your product is misbranded under the Act because you did not submit information that shows your device is substantially equivalent to other devices that are legally marketed.

Your product is also misbranded within the meaning of Section 502(b) because the label for the device does not bear the name and place of business of the manufacturer, in accordance with Title 21 of the Code of Federal Regulations (21 CFR), Section 801.1. You must also label the device in accordance with 21 CFR, Section 801.109.

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501 (h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to maintain device master records that include device specifications for all your products.
2. Failure to have an established quality system.
3. Failure to conduct planned and periodic audits of the quality assurance program in accordance with written procedures.
4. Failure to have established procedures for handling complaints and to maintain complaint files.
5. Failure to calibrate measuring and test equipment used in production.

You should know that these serious violations of the law 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 product, or assessing civil money penalties. Also, 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.

It is necessary for you to take action on this matter now. 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 the U.S. Food and Drug Administration, One Montvale Avenue, 4th Floor, Stoneham, MA 02180, Attention: E. Frank Gesing, Compliance Officer, New England District Office.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact E. Frank Gesing at (617) 279-1675, Extension 127.

Sincerely,

A handwritten signature in black ink, appearing to read "Gail T. Costello". The signature is fluid and cursive, with the first name "Gail" being the most prominent.

Gail T. Costello
Acting District Director
New England District

Enclosure

cc: Gastao G. Dacamara
Titan Manufacturing, Inc.
27 Maple Avenue
Holbrook, MA 02343