



94634d

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

**Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751**

**WARNING LETTER**

**FLA-04-25**

March 29, 2004

Randall L. Everett, President  
Diomedics, Inc.  
755 State Road 21  
North Melrose, Florida 32666

Dear Mr. Everett:

During inspections of your establishment located in North Melrose, Florida on June 25 and October 27-28, 2003 FDA Investigator R. Kevin Vogel determined that your establishment is a manufacturer and distributor of infrared therapy device(s) (Class II). These products emit energy in the infrared spectrum to provide topical heating for the purpose of elevating and/or maintaining tissue temperature and are devices, as defined by Section 201(h) [21 U.S.C. §321(h)] of the Federal Food, Drug, and Cosmetic Act (the Act).

The investigator documented violations of the Act causing the device to be adulterated within the meaning of sections 501(f)(1)(B) [21 U.S.C. § 351(f)(1)(B)] and 501(h) [21 U.S.C. §351(h)] and misbranded within the meaning of sections 502(a) and 502(o) [21 U.S.C. §352(a) and (o)] of the Act.

You do not have marketing clearance from FDA to promote and distribute the Pain-X-2000 as being effective for wound management, skin conditions, soft tissue injuries, joint conditions, fracture, chronic pain, head aches, and activation of acupuncture points, as listed in your internet promotions. The promotion of these device(s) for these claims contained in the Pain-X-2000 promotional material represent major modifications in the intended use requiring a new premarket notification submission. 21 CFR § 807.81(a)(3)(ii). Until you submit a section 510(k) premarket notification and FDA reviews it and notifies you that you may market your device for these intended uses, your product is also adulterated under § 501(f)(1)(B) of the Act because the law requires, and you do not have, an approved premarket approval application that shows your device is safe and effective.

Your Pain-X-2000 and other new infrared therapy models including Models 500, 1900, 3800, 5700, and Ultimate Portable; Boot System; Clinical A, B and C; the Infra-Red Bed; Model 3800 Headphones, Pads and Probe; Model 1900 Pads; Model 185 Pads, Probe; Model 19 LED Probe and LED Pad; and Model 38 LED Pad are also adulterated under section 501(f)(1)(B) [21 U.S.C. §351(f)(1)(B)] of the Act because you did not obtain premarket approval based on information developed by you that shows that the devices are safe and effective for the claimed intended uses.

Your devices are misbranded under section 502(o) [21 U.S.C. §352(o)] of the Act because a notice or other information respecting your devices were not provided as required by section 510(k), i.e., you did not submit information respecting the intended uses for claims made in your promotions and other new infrared therapy devices to the Food and Drug Administration.

The Pain-X-2000 is misbranded under 502(a) [21 U.S.C. §352(a)] because your website states that the device is "FDA Approved." The Pain-X-2000 was not reviewed under the pre-market approval process, therefore describing your device as "FDA approved" is false and misleading.

The investigator also documented significant violations from the Quality System (QS) Regulation, Title 21, Code of Federal Regulations (CFR), Part 820, and the Medical Device Reporting regulations, Title 21, CFR, Part 803. These violations cause the devices you manufacture to be adulterated within the meaning of Section 501(h) [21 U.S.C. §351(h)] of the Act.

Specifically, the investigator noted the following violations:

1. Your firm failed to document that the design of your device(s) followed the approved plan and that the design control requirements are maintained in the design history file as required by 21 CFR 820.30 (b) & (j) (FDA 483, Item #1 dated October 27-28, 2003 and FDA 483, Item #1 dated June 25, 2003).
2. Your firm failed to establish and maintain complete procedures to control the design process of device(s) to ensure that specified design requirements are met as required by 21 CFR 820.30 (a) and (g). Requirements to complete risk analysis were not included in the design control section of the Design Control Procedure, although it now includes descriptions of the design input, verification and validation for each device, it does not require that risk analysis be conducted for each design project (FDA 483, Item #4 dated October 27-28, 2003 and FDA 483, Item #4 dated June 25, 2003).

3. Your firm failed to establish and maintain procedures to assure that all purchased product and services conform to specified requirements as required by 21 CFR 820.50. Critical components such as LEDs and p.c. boards are not tested or inspected to assure that they meet specified requirements prior to processing (FDA 483, Item #2 dated October 27-28, 2003 and FDA 483, Item #2 dated June 25, 2003).

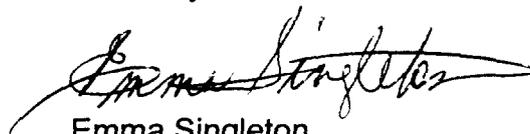
4. Your firm lacks complete training records for all employees as required by 21 CFR 820.25 (b). Documentation for the training of personnel who perform soldering operations was not complete (FDA 483, Item #3 dated October 27-28, 2003 and FDA 483, Item #3 dated June 25, 2003).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the steps you have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,



Emma Singleton  
Director, Florida District