



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Nashville District Office

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297 Plus Park Boulevard
Nashville, TN 37217

March 9, 1999

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CERTIFIED-RETURN RECEIPT REQUESTED

Mr. Greg Barbee
President
Medical Equipment Designs, Inc.
622 Rocky Branch Road
Rutledge, TN 37861

WARNING LETTER - 99-NSV-09

Dear Mr. Barbee:

During an inspection of your firm on December 3-4, 1998 and January 8, 1999 our investigator determined that you distribute a contract manufactured Class II Diathermy device marketed under the name of Meditherm. The inspection revealed that this device is adulterated within the meaning of Section 501(h) of the Federal Food, Drug, and Cosmetic Act (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 Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulation as specified in Title 21 Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practices (GMP) for Medical Device Regulations were superseded on June 1, 1997 by the Quality System Regulation. Since some of the records reviewed were dated prior to June 1, 1997, the deficiencies noted during the inspection are cross referenced to the 1978 GMP.

The inspection revealed deviations from Part 820 including the lack of an appropriate Device Master Record, failure to establish procedures to control design changes and no written complaint procedures.

Our records indicate that you obtained 510(k) clearance in 1990, to market your Meditherm device for the following indications: pain relief, decreasing muscle spasm, decreasing joint contracture, increasing blood flow, fibrositis, myositis, sub-acute or sub-chronic bursitis, chronic pelvic inflammatory disease, and chronic peri-arthritis. However, since 1990, you added rheumatoid

Mr. Greg Barbee - Page 2

arthritis, osteo-arthritis, sprains and strains, fractures, neuritis, peripheral vascular disease, otitis media, and pleurisy, indications you had agreed to remove as a condition for clearance of your 510(k). You have also added numerous other indications, including, but not limited to, bronchial asthma, concussions, gingivitis, frostbite, TMJ Disorders, mastitis, and ovarian insufficiency. Since 1990, you also modified the design of the Meditherm by introducing software to control the device. Major changes in the intended use of the Meditherm and design changes which could significantly affect safety or effectiveness, such as the introduction of software, require a new premarket notification (510(k)) submission (Title 21, CFR, Part 807, Section 81(a)(3)).

Because you do not have marketing clearance from FDA for your current Meditherm device, marketing your product is a violation of the law. In legal terms the product is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. 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. Until your firm submits a premarket notification submission for the current Meditherm and receives notice from FDA that it is substantially equivalent, the Meditherm is adulterated under the Act because it is a Class III device and does not have an approved application for premarket approval or an approved application for an investigational device exemption.

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. The specific violations noted in this letter may be symptomatic of serious underlying problems at your firm. You are responsible for investigating and determining the cause of the violations identified by the FDA.

Federal agencies are advised of the issuing of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no request for Certificate For Product For Export will be approved until the GMP violations related to your Diathermy device have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in

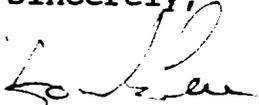
Mr. Greg Barbee - Page 3

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.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,



Howard E. Lewis
Acting Director
Nashville District

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Enclosure: 21 CFR Part 807.81