



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g1811d

CERTIFIED MAIL
RETURN RECEIPT REQUEST

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (714) 798-7600

WARNING LETTER

October 2, 2001

Peter J. Bonin
President
Medical Cables, Inc.
1340 Logan Avenue
Costa Mesa, CA 92626

WL-01-02

Dear Mr. Bonin:

During an inspection of your firm located in Costa Mesa, California, from August 8 to 17, 2001, our investigator determined that your firm packages and distributes electrode lead wire and patient cables manufactured for your company by another company pursuant to your design specifications. Electrode lead wires and patient cables are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection disclosed 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, and storage are not in conformance with the Good Manufacturing Practice (GMP) requirements for the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and implement procedures to control the design process of devices to ensure that specified design requirements are met [21 CFR 820.30(a)].
2. Failure to establish and implement a design and development plan describing the design and development activities, defining responsibility for implementation of these activities, and providing the identity and description of the interfaces with other groups or activities as appropriate [21 CFR 820.30(b)].
3. Failure to establish and implement procedures to ensure that a device's design input requirements are appropriate and address its intended use, including user/patient needs [21 CFR 820.30(c)].
4. Failure to establish and implement procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements [21 CFR 820.30(d)].

5. Failure to establish and implement procedures for planning and conducting reviews of the design results at appropriate stages of the device's design development [21 CFR 820.30(e)].
6. Failure to establish and implement procedures for verifying that design output meets the design input requirements [21 CFR 820.30(f)].
7. Failure to conduct a thorough risk analysis to identify and document any possible hazards associated with the design of the devices in both normal and fault conditions [21 CFR 820.30(g)].
8. Failure to establish and implement procedures to ensure the device design was correctly transferred into production [21 CFR 820.30(h)].

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 and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge that you have submitted to this office a response dated August 27th, 2001 concerning our investigator's observations noted on the form FDA 483. We have reviewed your response and have concluded that it is inadequate because it does not provide any supporting documentation of any proposed or corrective measures undertaken by your company to correct the observations and prevent the recurrence. Your letter only indicates that corrective measures will be undertaken within ninety days and provides no explanation why the observations could not be addressed in a timely manner.

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. Additionally, no pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Exportability will be approved until the violations related to the subject devices have been corrected.

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.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of

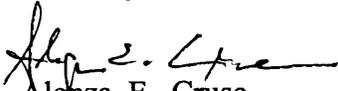
each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

If you have any questions relating to this letter please contact Senior Compliance Officer, Dannie E. Rowland at (949) 798-7649.

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612-2445

Sincerely,



Alonza E. Cruse
District Director
Los Angeles District Office

Cc: State Department of Public Health
Environmental Health Services
Attn: Chief, Food and Drug Branch
601 North 7th Street, MS-35
Sacramento, CA 94234-7320