

Cox **Chiropractic** associates, Inc.

James M. Cox, D.C., D.A.C.B.R.
James M. Cox, II, D.C.

May 4, 2000

Department of Health & Human Services
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health {HFZ-343}
5600 Fishers Lane
Rockville MD 20857

Re: Exemption and Variance Request:

To whom this may concern:

This request for variance is in regards to the performance of standard for the electrical lead wires and patient cable regulations, which go into effect May 9, 2000 This petition is requesting variance on the use of a particular lead cable plug.

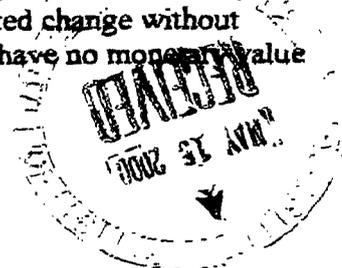
The name of the device is the Myofasciatron. It is in a class of muscle stimulators for use in physiological therapeutics for patient care. The device is to reduce muscle spasms as well as musculoskeletal pain.

The change of this particular lead cable that is used in this muscle stimulator appears to us to be unnecessary. The cable is attached to a plug, which is called a 1/4" phonoplug. This 1/4" phonoplug that plugs into the machine has been shown to be able to be plugged into any outlet used in the United States in clinical settings. I have spoken with Mr. Stewart Crumpler and he has stated to me that we may file for this variance due to the fact that this 1/4" phonoplug appears not to present any particular risks to the patient, due to the fact that it cannot be forced into an outlet. The risks being the ability to be plugged into a standard 120 wall outlet here in the United States. The 1/4" phonoplug does not have the capacity, due to its size, to be able to fit into a 120 outlet.

The inability to be inadvertently connected to a hazardous voltage appears to me to be a reason for granting a variance of this 1/4" phonoplug.

The manufacturer of this device has been contacted and is not producing any alternative lead wires at this time making it nearly impossible for us to make the mandated change without buying new equipment and selling what we have, which obviously will have no monetary value if there are no adapters to make it FDA compliant.

*mfd by
Electro Therapeutic Co.
Firm is not registered, or listed
& has no 510(k).*



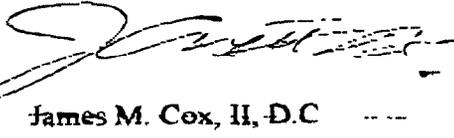
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We look forward to your written response to this variance. Thank you for your time and consideration in this matter. Any further information that is needed from us concerning the granting of the variance request may be directed to our office.

Sincerely,



James M. Cox, II, D.C.

JMC/dt

