



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

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PHILADELPHIA DISTRICT

800 U.S. Customhouse
2nd and Chestnut Str
Philadelphia, PA 19106

Telephone: 215-897-

WARNING LETTER

November 12, 1996

97-PHI-03

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Roy Allen, Chief Executive Officer
Dentronix, Inc.
101 Steamwhistle Drive
Ivyland, PA 18964

GEN.	SPEC.
RELEASE	
F# _____	DATE 11/14/96
Reviewed by: <i>James M. Campbell</i>	

Dear Mr. Allen:

From September 25 through November 10, 1996, Philadelphia District Investigator James P. McEvoy conducted an inspection of your medical device manufacturing facility. The orthodontic instruments and dry heat sterilizers you manufacture are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic (FD&C) Act.

The inspection revealed that the Medtronix M300 Dry Heat Sterilizer (M300) is misbranded within the meaning of Section 502(o) of the FD&C Act in that you have not submitted a notice or other information as required by Section 510(k) of the FD&C Act prior to introducing the device into interstate commerce for commercial distribution. As a result, the M300 is also adulterated within the meaning of Section 501(f) (1) (b) of the FD&C Act in that it is a Class III medical device under Section 513(f) and does not have an approved application for premarket approval in effect pursuant to Section 515(a) or an approved application for an investigational device exemption in effect under Section 520(g). Investigator McEvoy noted during the inspection that your firm has marketed the M300 in interstate commerce since ~~_____~~

In addition, devices manufactured by your firm are adulterated under Section 501(h) of the FD&C Act in that the methods used in, or the facilities or controls used for, their manufacturing, packing, storage or installation are not in conformance with Current Good Manufacturing Practice (CGMP) regulations codified in Title 21 Code of Federal Regulations (21 CFR) Part 820. Specifically, the inspection revealed that you have failed to conduct periodic audits of the quality assurance program in accordance with written procedures [21 CFR 820.20 (b)].

bcc:HFA-244/HFC-210 (CFR 2518439)/HFI-35 (PURGED)/HFZ-333 (C. Niebauer)/HFR-MA100/HFR-MA150/Montgomeryville, R.P./HFR-MA195/EF/Warning Letter File/JTD/KMC/Distributed by:

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Further, our review of the M300 labeling that Investigator McEvoy collected during the inspection revealed that the product is misbranded within the meaning of Section 502(f) (1) of the FD&C Act in that its labeling indicates that the device is appropriate for use in sterilizing instruments when the device's design limits its sterilization capabilities to talc. However, we acknowledge your actions to correct the labeling for the units currently in commercial distribution by deleting any references to instrument sterilization.

We also acknowledge your decision to cease marketing the M300 until you can submit and receive clearance for its premarket notification (510(k)). However, devices currently in commercial distribution are misbranded as indicated above and will continue to be misbranded until clearance is received.

This letter is not intended to be a all-inclusive list of deficiencies at your facility. As top management, it is your responsibility to ensure adherence to each requirement of the FD&C Act and regulations.

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

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 pending applications for premarket approval (PMA's) or export approval requests will be approved and no premarket notifications (Section 510(k)'s) will be found to be substantially equivalent for products manufactured at the facility in which the above CGMP violations were found until the violations have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in FDA's initiation of regulatory action 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 as to 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 the underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be

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completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. The corrective action should also address the status of the M301 devices currently in commercial distribution.

Your reply should be sent to the attention of Karyn M. Campbell, Compliance Officer, at the address noted on the letterhead.

Sincerely,



Diana J. Kolaitis
District Director