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9/17/97



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

431

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

SEP 17 1997

VIA FEDERAL EXPRESS

Dr. Deborah Sorgnard
President
Matrix Electromedical, Incorporated
4208 Arcata Way
North Las Vegas, Nevada 89030

Re: ElecDT & VacuPulls,
K930264; MMR 190i Microwave
Diathermy K895000

Dear Dr. Sorgnard:

The Food and Drug Administration (FDA) has reviewed promotional materials for the ElecDT and VacuPulls, and the MMR 190i Microwave Diathermy devices. The ElecDT and VacuPulls are manufactured by [REDACTED]. The MMR 190i is manufactured by [REDACTED]. All three products are distributed by Matrix Electromedical, Incorporated (Matrix), and are devices as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The Matrix ElecDT and VacuPulls have been cleared under section 510(k) of the Act and are electrical signal generators which apply sinusoidal current through two pair of contact electrodes using temporal interference patterns to stimulate peripheral nerves for the purpose of providing pain relief and to stimulate motor nerves for the purpose of muscle rehabilitation. Additionally, your 510(k) submission also contained the following intended uses: "for adjunctive use in post-traumatic pain syndromes; for management and symptomatic relief of chronic (long-term) pain; as an adjunctive treatment in the management of post-surgical pain problems; relaxation of muscle spasms; prevention or retardation of tissue atrophy; increasing local blood circulation; muscle re-education; immediate post-surgical stimulation of calf muscles to prevent phlebothrombosis; and maintaining or increasing range of motion."

The MMR 190i is a microwave diathermy device and has been cleared for applying therapeutic deep heat by use of electromagnetic energy in frequency bands between 915 MHz to 2,450 MHz for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

We have reviewed the following Matrix promotional brochures and flyers: (1) Matrix...Into the Future, ElectDT Electromedical Differential Treatment, (2) HealthCare Reform ...Preparing for the Possibilities, and, (3) MMR 190i. Medical Microwave Resonance. These materials indicate that Matrix is promoting the above

devices for intended uses that go beyond the clearances granted by the agency.

Your brochure, Matrix Into the Future, discusses the Matrix Bioelectric Treatment System and contains pictures of both the ElecDT and MMR 190i devices, and discusses intended uses that have not been cleared. We are unable to determine which intended uses are attributed to the ElecDT or the MMR 190i because both devices are represented by their pictures. The claims made in the brochure would imply that both devices are capable of achieving these results. The following uses are listed in the brochure:

- pain with impaired circulation;
- polyneuropathy;
- ischemia and occlusive disease;
- vascular headaches;
- arthritis/arthrosis;
- postherpetic neuralgia;
- nerve root lesions;
- reflex sympathetic dystrophy (RSD);
- carpal tunnel syndrome (CTS).

The back page of the same brochure discusses 5 physiological mechanisms of action for pain management ("Matrix Electroceutical Application") and implies that the Matrix ElectDT and MMR190i achieve their physiological effects through these mechanisms. They are: counter irritation (gate control theory); release of neuropeptides (endorphin, serotonin, enkephalin, etc.); influence on pain substrates (substance P, prostaglandins, etc.); neuron blockade; and influence and support of regeneration (cAMP, second messenger). Matrix has not submitted any data to the Agency supporting these mechanisms.

Your brochure also states that when Matrix Bioelectric Therapy is combined with other more traditional therapies, it results in enhanced effectiveness of pharmaceuticals, possible decrease in pharmaceutical dosage and toxicity, and quicker resolution to asymptomatic status. None of these claims have been cleared or supported to the agency.

Other claims specific to the ElecDT which have not been cleared by the agency include: "provide potent analgesic effects via neuron blockade, and has been shown to be beneficial in the treatment of circulatory disorders such as venous stasis, lymphatic impairment and microangiopathy." Other claims described in the HealthCare Reform brochure include: upper back disorder, non-invasive sympathetic block- stellate ganglion, "produce profound effects on the circulation, provide potent analgesia, and support regeneration processes at the cellular level," and claims that pharmacotherapy effects are enhanced.

These expanded claims represent a major modification in the intended use(s) of the devices as defined under 21 CFR 807.81(a)(3)(ii) and require the submission of a new 510(k).

The ElectDT, and MMR 190i devices are adulterated within the meaning of section 501(f)(1)(B) of the Act in that they are Class III devices under section 513(f), and do not have approved applications for premarket approval (PMA) in effect pursuant to section 515(a), or approved applications for investigational device exemptions (IDE's) under section 520(g).

The ElectDT and MMR 190i devices are also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended uses of the devices was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the devices were not found to be substantially equivalent to a predicate device.

Our records do not show that you obtained premarket clearance for a device referred to in your HealthCare Reform brochure as the VasoPulse® before you began offering this device for sale. The VasoPulse® is misbranded under section 502(o) of the Act in that the device was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510, was not included in a list required by section 510(j), a notice or other information respecting the device was not provided to FDA as required by section 510(k), and the device was not found to be substantially equivalent to a predicate device.

Additionally, the VasoPulse® is also adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

We note that none of your promotional labeling includes a listing of the indications, and any relevant hazards, contraindications, side effects, and precautions for the approved use. Inclusion of these items in the labeling of devices is required under the provisions of 21 CFR 801.109(d). Matrix should immediately revise its literature so that these items are included.

We also note that the language used in your brochures for the prescription legend is incorrect. The correct language, as defined under 21 CFR 801.109, should read: "Caution: Federal law restricts this device to sale by or on the order of a _____," the blank to be filled by the word "physician," "dentist," "veterinarian," etc.

Finally, we note that your promotional brochures make reference to FDA's clearance/approval and to the existence of a 510(k) as in the phrase, "and are FDA approved for sale." We also find the 510(k) reference in your flyer for the MMR 190i microwave diathermy device. Reference to FDA, in advertisements or other promotional materials for medical devices is prohibited by the Act and represents misbranding under section 502(a). The reference for this may be found under 21 CFR 807.97, "any representation that creates an impression of official approval because of complying with the premarket notification regulations is misleading and constitutes misbranding." All references to FDA approval and/or 510(k) in your promotional

materials should therefore cease immediately.

This letter is not intended to be an all-inclusive list of deficiencies associated with your ElectDT and MMR 190i devices. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

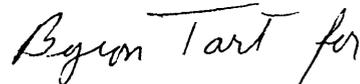
You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. 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.

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's San Francisco District Office. Please send a copy of your response to the District Director, Food and Drug Administration, San Francisco District Office (HFR-PA100), 1431 Harbor Bay Parkway, Alameda, California 94502-7070.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health