



JAN 30 2000

Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

**WARNING LETTER****VIA FEDERAL EXPRESS**  
**VIA FACSIMILE**

Mr. Gary Binder  
President  
Voyager Medical Corporation  
4380 SW Macadam Avenue  
Portland, Oregon 97201

Re: Pulsar Model 777 Therapeutic  
Massager and Vibrator, K940543

Dear Mr. Binder:

The Office of Compliance (OC), Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) has reviewed your web site at the Internet address: <http://www.voyagermedical.com> for the Pulsar Model 777 Therapeutic Massager and Vibrator (Pulsar 777). This product is manufactured by Voyager Medical Corporation (Voyager Medical) and is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

In your original 510(K) submission of January 17, 1994, you identified the Pulsar 777 as a therapeutic massager. The Pulsar 777 was subsequently cleared by the agency on April 21, 1994 as a therapeutic massager and is intended for the relief of minor muscle aches and pains, increase in local blood circulation, and to relax muscles locally. Additionally, in 1998, therapeutic massagers were also granted permission by FDA to claim a temporary reduction in the appearance of cellulite.

On January 28, 2000 this office sent you a letter advising that certain claims on your web site had not been cleared by the agency and would require the submission of a new 510(k). On April 11, 2000, Voyager Medical responded and agreed to remove all violative claims from your web site. It appears however, that your current web site at the internet address: <http://www.voyagermedical.com> continues to contain the violative claims that you previously agreed to remove. These claims include, but are not limited to, the following:

- Us the Pulsar to treat headaches,...backache,...and inflammations

- Use it conjunction with traditional methods to heal quickly and comfortably, from the agony of a major injury to the annoyance of an ugly bruise
- ...Pulsar combats the painful symptoms associated with a variety of temporary and chronic conditions, from simple strains to fibromyalgia
- The same holds true for a number of chronic conditions familiar to computer users: RSI (Repetitive Stress Injury); RSS (Repetitive Stress Syndrome); and CTD (Cumulative Trauma Disorder)
- The Pulsar may be used to relieve the pain and inflammation of the wrists, hands, arms, shoulders, and neck associated with tendonitis, Carpal Tunnel Syndrome (CTS), Thoracic Outlet Syndrome (TOS), and other repetitive stress-related injuries

Promoting the Pulsar 777 Therapeutic Massager for claims of treating backaches, headaches, inflammations, acute or chronic conditions such as fibromyalgia, Repetitive Stress Injury, Repetitive Stress Syndrome, Cumulative Trauma Disorder, Thoracic Outlet Syndrome, relief of pain associated with Carpal Tunnel Syndrome, other repetitive stress-related injuries, or tendonitis causes the Pulsar 777 to be 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).

The Pulsar 777 is 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 use of the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the device was not found to be substantially equivalent to a predicate device.

This letter is not intended to be an all-inclusive list of deficiencies associated with your Pulsar 777 device. 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

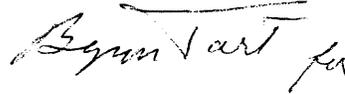
working days, state the reason for the delay and the time within which the corrections will be completed.

Additionally please supply this office with data to support claims that the Pulsar 777 uses low frequency, subsonic waves to treat pain, that it can effect pain by stimulating nerve endings, that it can aid in the body's long-term healing process, and that it can flush out toxins by allowing oxygen to saturate the area and bring vital nutrients, minerals, and hormones to the area.

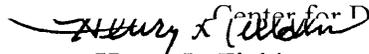
Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Seattle District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Seattle District Office (HFR-PA300), 22201 23<sup>rd</sup> Drive, S.E., Bothell, Washington 98021-4421.

Sincerely yours,



Larry D. Spears  
Acting Director  
Office of Compliance  
Center for Devices and



Henry L. Fielden  
District Director  
Cincinnati District