Inspections, Compliance, Enforcement, and Criminal Investigations

NETPRODUCTSTORE INC, DBA Afton Communications 9/11/09

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

SEP 11 2009

WARNING LETTER

VIA FEDERAL EXPRESS

Bud Meachum AKA Harold Meachum
Owner
Netproductstore, Inc. DBA Afton Communications
80 Gilman Ave., Suite 21
Campbell, CA 95008-3026

RE: Rhythm Touch Q 2-Way
Refer to GEN0900908 when replying to this letter.

Dear Mr. Meachum:

The Food and Drug Administration (FDA) has learned that your firm is marketing the Rhythm Touch Q 2-Way in the United States without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

The Office of Compliance in the Center for Devices and Radiological Health (CDRH) reviewed your websites, at http://www.3dnut.com and http://www.netproductstore.com, for the Rhythm Touch Q 2-Way product on September 2,2009. This product is a medical device within the meaning of section 201(h) of the Act, 21 U.S.C. § 321 (h), because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body.

This device is adulterated under section 501(1)(1)(B) of the Act, 21 U.S.C. § 351(1)(1)(8), because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g), of the Act, 21 U.S.C. § 360j(g). This device is also misbranded under section 502(0) of the Act, 21 U.S.C. § 352(0), because you did not notify the agency of your intent to introduce the device into commercial distribution for the new intended uses discussed below, as required by section 510(k), 21 U.S.C. § 360(k), and 21 C.F.R. § 807.81(a)(3)(ii). For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency. The kind of information you need to submit in order to obtain approval or clearance for your device is described on the Internet at http://www.fda.gov/cdrh/devadvicc/3122.htm1. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

Specifically, the Rhythm Touch Q 2-Way was cleared via premarket notification (510(k)) K032178 for relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, and for maintaining or increasing range of motion. The Rhythm Touch Q 2-way has also been cleared via premarket notification K063743 for temporary relief of pain associated with sore and aching muscles in lower back due to strain from exercise or normal household and work activities.

Your websites represent or suggest that the Rhythm Touch Q 2-Way is intended for use in the treatment of the following diseases: anemia, headaches, neuropathy, arthritis, hyper mobility syndrome, peripheral nerve palsy, asthenia, impotence, plantar faciata, insomnia, sciatic nerve trauma, lethargy, sciatic neuralgia, chronic pain, slipped disc, constipation, stiff neck, degenerative disc disease, menoxenis, diabetes, migraine headaches, spinal "stinosis" [sic}, fatigue, stomach ache, fibromyalgia, multiple sclerosis, tendonitis, gastroptosis, myalgia, uretiritis, hand tremor, "neurasthesia" [sic}, and varicose veins. These represent major changes or modifications in the intended use of the device that require a new 510(k). See 21 CFR 807.81(a)(3)(ii).

The Office of Compliance requests that Netproductstore Inc. immediately cease marketing the Rhythm Touch Q 2-Way for unapproved uses the same as or similar to those described above on your websites at http://www.3dnuLcom, http://www.netproductstore.com, and any other websites through which your firm is doing business. You should take prompt action to correct these violation(s). Failure to promptly correct these violation(s) 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 money penalties.

Please submit a written response to this letter within 15 working days from the date you receive this letter, describing what steps you have taken to correct the problem and how you plan to prevent this from happening again. Please list all promotional materials for the Rhythm Touch Q 2-Way with claims for unapproved uses such as those described above, and explain your plan for discontinuing such claims. Please direct your response or any questions you may have to: Jennifer R. Medicus, Acting Branch Chief, Radiology, Anesthesiology, and Neurology Devices Branch, Office of Compliance, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, Maryland 20993-0002, facsimile at (301) 847-8128. We remind you that only written communications are considered official.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that your promotional materials for the Rhythm Touch Q2-Way comply with each applicable requirement of the Act and FDA implementing regulations.

Sincerely yours,

/s/

Timothy A. Ulatowsk
Director
Office of Compliance
Center for Devices and
Radiological Health

cc: Young In Kim, President
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