U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

UROMATRIX Medical Systems (A Pos-T-Vac Medical Company)

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Atlanta District Office
60 Eighth Street, NE
Atlanta, GA 30309

April 5, 2011

VIA UNITED PARCEL SERVICE

Edward Stewart, CEO/President
Pos-T-Vac, Inc.
1701 North 14th Avenue
Dodge City, KS 67801

WARNING LETTER
(11-ATL-07)

Dear Mr. Stewart:

During an inspection of your firm located in Martinez, Georgia, on November 30, 2010, through December 2, 2010, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures (relabels) The Medical Extender Device (also known as the Andro Penis Extender) and distributes the GeeWhiz Incontinence Management Device and EREC-TECH Vacuum Therapy System. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body

This inspection revealed that The Medical Extender Device is adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

We received your response dated December 15, 2010, concerning our investigator's observations noted on th Form FDA 483, List of Inspectional Observations, that was issued to you. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

Failure to establish and maintain adequate procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example, there is no documented complair handling procedure. Complaints are not evaluated to determine whether the complaint represents an event requiring MDR reporting. Complaints are not reviewed and evaluated to determine if an investigation is necessary.

We reviewed your response and conclude that it is not adequate because you have not provided any complair handling procedures, nor have you performed a review and/or evaluation of previously received complaints.

Our inspection also revealed that your Medical Extender Device is misbranded under section 502(t)(2) of the Act 21 USC 352 (t)(2), in that your firm failed or refused to furnish material or information respecting the devices that is required by under section 519 of the Act, 21 USC 360i, and 21 CFR Part 803 – Medical Device Reporting (MDR) Regulation. Significant deviations include, but are not limited to, the following:

Failure to develop, maintain, and implement written MDR procedures, as required by 21 CFR 803.17. For example, it was confirmed, during your recent inspection, you have not developed, maintained or implemented an MDR procedure, as required by 21 CFR 803.17.

We have received your response dated December 15, 2010, and determined that it is inadequate. You have not implemented written MDR procedures.

Our inspection also revealed that your GeeWhiz Incontinence Management Device and EREC-TECH Vacuum Therapy System are misbranded under section 502(t)(2) of the Act 21 USC 352 (t)(2), in that your firm failed or refused to furnish material or information respecting the devices that is required by under section 519 of the Act, 21 USC 360i, and 21 CFR Part 803 – Medical Device Reporting (MDR) Regulation. Significant deviations include, but are not limited to, the following:

Failure to permit any authorized FDA employee, at all reasonable times, to access, to copy, and to verify your complaint records, as required by 21 CFR 803.18(d)(3). For example, complaints received after September 1, 2009, and maintained in your File Maker Pro database system, could not be filtered and retrieved for review during your 2010 inspection.

We have reviewed your response dated December 15, 2010, in regards to describing a plan to implement a filing system for complaints, as required by 21 CFR 803.18(d)(3) and have concluded that it is adequate.

Our inspection also revealed that The Medical Extender Device is adulterated under section 501(f)(1)(B) of th Act, 21 U.S.C. 351(f)(1)(B), 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). The device is also misbranded under section 502(o) the Act, 21 U.S.C. 352(o), because you did not notify the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C 360(k). 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. [21 CFR 807.81(b)] 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/devadvice/3122.html[1]. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

We have reviewed your response dated December 15, 2010, and determined that it is inadequate. You have not addressed marketing of The Medical Extender Device for conditions other than Peyronie's Disease. You also have not provided a plan for the disposition of devices that you retain.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations 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. Also, 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, premarket approval applications for Class III devices to which the Quality System regulation violations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) business days from the date you receive this letter of the specific steps you have taken to correct the noted violations, as well as an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions you have taken. If your planned corrections and/or corrective actions will occur ove time, please include a timetable for implementation of these activities. If corrections and/or corrective action cannot be completed within 15 business days, state the reason for the delay and the time within which these

activities will be completed. Your response should be comprehensive and address all violations included in this WL.

Your response should be sent to Serene N. Ackall, Compliance Officer at 60 8th Street NE, Atlanta, GA 30309. If you have any questions about the content of this letter please contact Ms. Ackall at 404-253-1296.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely,
/S/
John R. Gridley
District Director

Cc:
Mr. Robert White
President and Chief Executive Officer
UROMATRIX Medical Systems
A Pos-T-Vac Medical Company
4811 Technology Drive
Martinez, GA 30907-2606

Links on this page:

0. http://www.fda.gov/cdrh/devadvice/3122.html