Date: February 28, 1995

From: Chemist/Consumer Safety Officer, OC/DOE3/Orthopedic, Restorative, and Anesthesiology Devices Branch (HFZ-343)

Subject: Amendment to K894435 VAT-TECH, Inc. Vertebral Axial Traction (VAX-T) Table

To: Marie A. Schroeder, M.S., P.T., Chief, Restorative Devices Branch, DGRD

Through: Joyce Moultry, Premarket Notification Section, Document Mail Center

This submission is a response to my letter of January 11, 1995 (attached).

The reason we sent this letter is that since 8/94 the Newark and Orlando District Offices have received numerous consumer calls concerning whether a VAX-D device had been cleared for marketing. Consumers also asked about its labeling claims.

A check of the 510(k) files revealed that a VAX-T device had been cleared for marketing and in a letter dated March 27, 1991 (attached), the sponsor amended the this 510(k) to correct the procode and change the name of the device to VAX-D. However, this letter did not include a description of the device, so it is not clear whether the company had made any changes to it.

A cursory review of the sponsor's response to the January 11, 1995, letter shows that it has modified the design of the device to include a software-driven computer for data collection and also has added claims to the promotional material. In addition the firm should be asked to delete the statement "The VAX-D Therapeutic Table is in compliance with Food & Drug regulations for use in the United States" in the promotional brochure "The Non-Surgical Alternative to Back Pain Treatment - VAX-D Therapy". This statement implies that FDA has approved this device and constitutes misbranding under 21 CFR 807.97.

Please review this material and decide if a new 510(k) is needed. Thank you.

Elizabeth A. Riegel

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