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VAX-D
VERTEBRAL AXIAL DECOMPRESSION

Mr. Robert Chiesler,
Office of Device Evaluation,
1319 Piccard Dr., HFZ-403,
Rockville, Md., 20850

March 27, 1991

Dear Mr. Chiesler;

I am writing for clarification of our 510[k] submission file No. K904435. The notification received from the Office of Device Evaluation identified the product as a " Vax-T Pelvic Traction Belt". This has caused some confusion in as much as the device is in the category of Powered Traction Equipment, code No. ITH and the device is identified as a "VAX-D Therapeutic Table". In discussing this matter with the Division of Small Manufacturers Assistance, they reviewed the file and informed me that the registration is incorrectly listed under the code [IPI] which is apparently for Powered Wheelchairs.

I regret not bringing this to your attention before this time. Since our submission we have been engaged in clinical trials with the device at the HCA Rio Grande Regional Hospital, in McAllen Texas, and at the University Hospital, London Ontario, and have now reached the stage of processing to market the equipment. It was at this stage that the notification from your office was retrieved from our files and the problem was noted.

We are very concerned about the confusion in terminology and coding because referral to our registration number and notification could create a problem with some potential clients who request information on the FDA status.

The Division of Small Manufacturer recommended that we contact your office to have this matter corrected as soon as possible because if they receive any requests regarding the registration their computer file lists the product under the IPI code . We respectfully request your attention to this at your earliest convenience in order to correct the listing and the identification of our product on the notification from your Office.

Sincerely;

Allan Dyer, Phm.B., B.Ed., Ph.D., M.D.
President

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 11 1995

Allan Dyer, Ph.D., M.D.
President
VAT-TECH Inc.
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Toronto, Ontario
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Dear Dr. Dyer:

We have recently reviewed your letter dated March 27, 1991, to Robert Chissler in the Office of Device Evaluation. In this letter you refer to the Vertebral Axial Traction (Vax-T) Table as the Vertebral Axial Decompression (Vax-D) Therapeutic Table. The subject of K894435 is the VAX-T Table. Because of this discrepancy and other concerns we believe you need to update this 510(k).

You must clarify how the Vax-D is similar to the Vax-T and whether it has the same intended uses.

Please send a complete package which references K894435 and includes a description of the Vax-D and a comparison of it to the Vax-T as well as labeling and promotional materials for both the Vax-T and the Vax-D devices to:

Document Mail Center
Food and Drug Administration (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Sincerely yours,

Elizabeth A. Riegel

Elizabeth A. Riegel
Orthopedic, Restorative, and
Anesthesiology Devices Branch
Division of Enforcement III
Office of Compliance
Center for Devices and
Radiological Health

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