

K451622/A

**ECG**

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June 27, 1995

FDA/CDRH/OGE/DHC  
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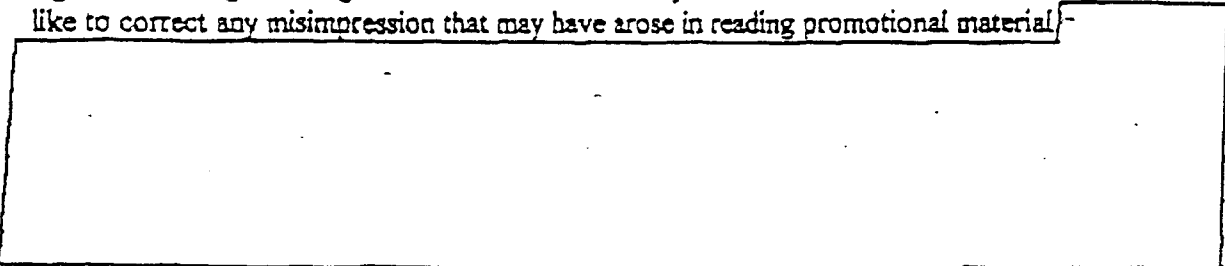
Attention: **Document Control Clerk**  
Type of Submission: **510(k) Notification (K951622)**  
Product: **VAX-D\* Therapeutic Table**  
Reason for Submission: **Modification of Labeling from Original Submission (K894435)**

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27 JUN 95 10 10  
FDA/CDRH/OGE/DHC

Dear Sir/Madam:

In accordance with Section 510 (k) of the Federal Food and Drug Cosmetic Act as amended, and in conformance with Title 21 CFR, Part 807, this Pre-market Notification is being submitted for the **VAX-D\* Therapeutic Table**. VAT-TECH INC. is submitting this 510(k) in response to the April 21, 1995 letter from Paul R. Benninger, M.D., Director of the Division of General and Restorative Devices. Dr. Benninger's letter and our initial response are in TAB 5.

Two reasons were cited in this letter in support of the need for this submission. The first was that unlike the original 510(k) (K894435), "...the VAX-D table is computerized, which constitutes a significant change in design that could affect the safety or effectiveness of the device". We would like to correct any misimpression that may have arose in reading promotional material.



The second reason cited in this letter was that "claims for decompression of the intervertebral disk, as measured by the lowering of intradiscal pressures, represents a new intended use." The intended uses cited in VAT-Tech's original 510(k) (K894435) are as follows:

*See 11-11-95*  
*See 200081*

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"This therapy provides a primary treatment modality for the management of pain and disability for patients with incapacitating low back pain. It has been found to provide relief in a variety of conditions involving anatomical dysfunctions of the lumbar spine that generate localized low back pain as well as peripheral radiation, including patients with protruding or herniated intervertebral discs as well as those with acute facet problems".

These still constitute the indications for therapy for this device. Reference to "decompression" in VAT-TECH's literature is an attempt to explain the mechanism of action of the VAX-D Therapeutic Table, shown by published studies referenced in this submission. Patients are prescribed this form of therapy because it helps relieve low back pain not because they would like their vertebrae "decompressed". We, therefore, do not understand the basis for FDA's concern.

Never-the-less, VAT-TECH, INC. is submitting this 510(k) in order to resolve the questions raised. In order to facilitate FDA review, the sponsor VAT-TECH, INC., has done the following:

1. We have enclosed a completed *Premarket Notification (510(k)) Checklist for Acceptance Decision* form (TAB 4).
2. In accordance with the requirements of SMDA (1990), we have enclosed a *Summary of Safety and Effectiveness* information upon which the substantial equivalence determination is based (TAB 10).
3. The Sponsor has signed the "TRUTHFUL AND ACCURATE STATEMENT" (TAB 2).
4. We have completed the *Premarket Notification COVER SHEET* (TAB 3)
5. This submission follows the format provided in FDA's December 30, 1994 *DRAFT GUIDANCE DOCUMENT FOR THE PREPARATION OF PREMARKET NOTIFICATION [510(k)] APPLICATIONS FOR ORTHOPEDIC DEVICES*.
6. We completed FDA's 510(k) "Substantial Equivalence Decision-Making Process" Flow-Chart (TAB 8).

Sincerely,



Norman F. Estrin, Ph.D., RAC  
President

