

K951622/S4

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**VAD**

April 22, 1996

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (5PZ-481) FDA/CDRH/OBE/DMC  
9200 Corporate Boulevard  
Rockville Maryland 20850

1 May 96 09 39

Re: K951622  
VAD-D Therapeutic Table

Response to deficiency  
letter dated April 10, 1996

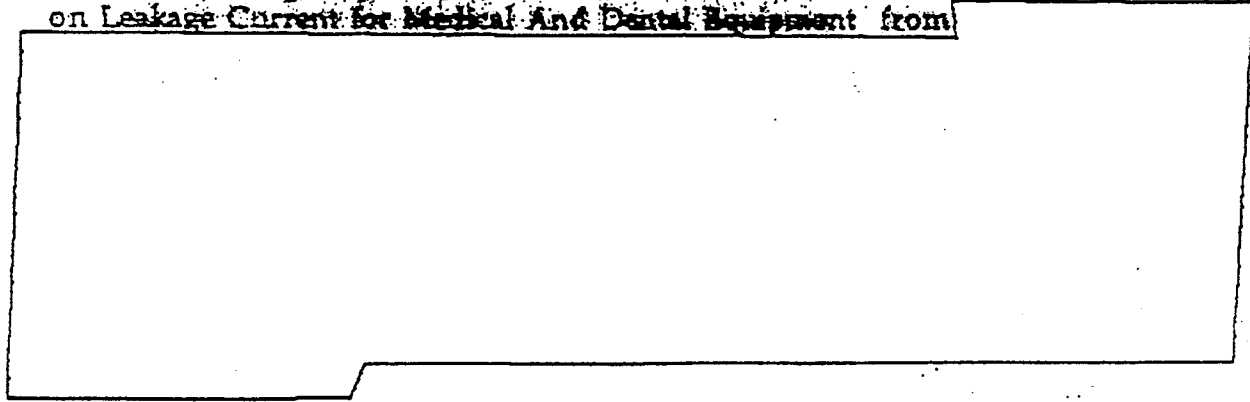
Mr. Andrew Novick, M.A., P.T  
Restorative Devices Branch  
Division of General and  
Restorative Devices  
Office of Device Evaluation

RECEIVED  
31 APR 96 10 5  
FDA/CDRH/OBE/DMC

Dear Mr. Novick:

This is a letter in response to your deficiency letter and request for information dated April 10, 1996. We will respond to each of the issues and questions individually.

1. I am enclosing for you the section from the current UL 544 Standards Manual on Leakage Current for Medical And Dental Equipment from



2. When we refer to 'decompression' we will define, or clarify it with the language:

"decompression of the intervertebral discs and facet joints, that is unloading, due to distraction and positioning."

3. As stated in our previous letter the reference to " maintenance therapy" has been deleted.

4. The statements regarding 'diffusion gradients and healing process' was used for discussion purposes and will not appear in our labeling or promotional material.

**VAT-TECH**

5. The term "unique" has been discontinued in our labeling and promotional material.

6. The reference to "almost all patients" and "most people" will be deleted from our labeling and promotional material.

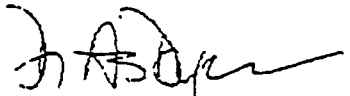
7. The reference "about 10 to 15 sessions are usually recommended as a course of therapy" will be deleted from our labeling and promotional material. References to "an average" number of sessions has been deleted. The promotional material will use the language "A Vax-D clinic practitioner will determine your course of therapy and whether or not you are a candidate for VAX-D Therapy".

8. The term "significant (ly)" will be deleted from our labeling and promotional material.

We are supplying the requested information in hopes to resolve all questions in your review, and would appreciate having the review completed expeditiously.

Thank you.

Sincerely,



A. E. Dyer, Phm.B., B.Sc., M.D., Ph.D.  
President