

VAX-D

K951622/5²

**VAX -D[®] THERAPEUTIC TABLE
K951622**

RESPONSE TO DEFICIENCY LETTER (SEPTEMBER 14, 1995)

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VAT-TECH INC.
38511 US HWY 19 NORTH
PALM HARBOR FL 34684

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September 28, 1985

Director, FDA
Center for Drug Evaluation and Research
Food and Drug Administration
Washington, DC 20543
FDA Corporate Blvd.
Rockville, MD 20850

RECEIVED
2 Oct 95 11 00
FDA/CDRI/DOE/DMA

Attention: Director, Center for Drug Evaluation and Research

Reference: [Redacted]

Product: VAX-B Therapeutic Table

Sponsor: VAX-TECH INC.

Establishment Registration Number: 033477

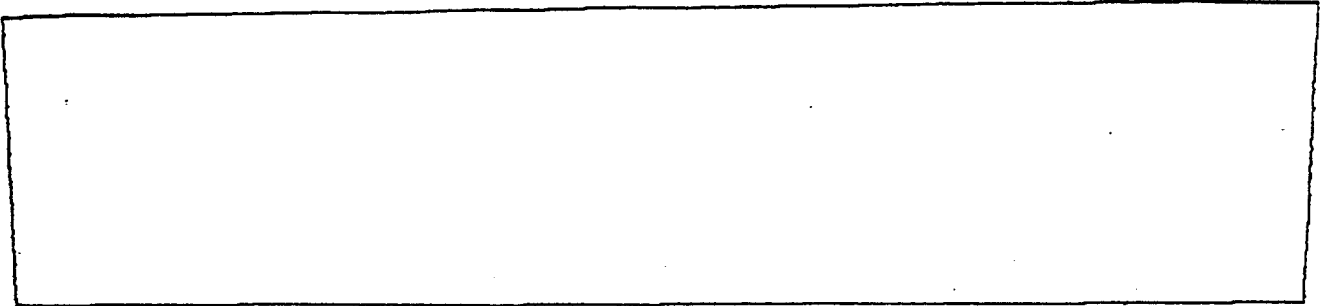
Sponsor Identification: Allen E. Dyer, Ph.D., M.D.
VAX-Tech, Inc.
300 N. W. 10th Street
Miami Beach, Florida 33134

Dear Sir/Madam:

On September 23, 1985, your request for FDA review of the use of VAX-B TABLETS
[Redacted]
by a letter dated September 27, 1985 from [Redacted]. The product information is as follows:

- 1. Please provide information about the fire retardant properties of the cushions.

TAB 1 contains the specifications for the VAX-D™ Therapy Table and cushions, including those for fire retardancy.



- 3. Clarify which claims Vat-Tech intends to make in this submission and supply supporting clinical data.

In the April 20, 1995 letter from Paul R. Beninger, M.D., only one claim was questioned. The letter states that "claims for decompression of the intervertebral disc, as measured by the lowering of intradiscal pressures, represents a new intended use." We stated our disagreement with this conclusion in the June 27, 1995 cover letter for our 510(k) submission since references to "decompression" explain the mechanism of action for the intended use of "helping to relieve low back pain". In addition, our original cleared submission for this device (K894435) uses the term "Distal intervertebral spaces", a term which has the identical meaning to "Decompress intervertebral discs" or "Vertical Axial Decompression". See the comparison table in TAB 3 of this submission. (For convenience in the IUDs we refer to the device cleared in K894435 as the "VAX-T" even though its name was changed to the "VAX-D" soon after clearance.)

b one claim

c just. k. ratio for claim

Vat-Tech has, in order to expedite clearance of this submission, supplied clinical data in the K951622 submission which is ample to support use of these terms. Please see the study, *Effects of Vertical axial decompression on intradiscal pressure* by Gustav Ramos, M.D. and William Martin, M.D., *Journal of Neurosurgery* 81: 350-353, 1994. A reprint of this paper is included on page 53 (TAB 6U) of the June 27, 1995 510(k) submission (K951622). Copies of the brochures included with K894435 are also included in TAB 4 of the present submission, for your convenience. Copies of the proposed patient and practitioner brochures for K951622 appear on pages 89 - 102 (TAB 9) of the June 27, 1995 submission.

article ref.

While there are changes in the wording of some terms used in the 1989 brochures for the VAX-T compared with the proposed brochure and Manual for the 1995 submission, the changes are not fundamental (TAB 3). Alternative wording for the same intended use and indications for use are grouped together. The changes and additions are meant to clarify or modernize terminology consistent with current medical practice. For example, the term

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"peripheral radicular" has been used for K894435 and K961622. Since "radicles" and "nerve root defects" are generally accepted as qualifications of peripheral radicular, Vni-Tech would like the flexibility to use these terms as well. The term "peripheral radicular" is being replaced in medical literature with the more accurate term, "peripheral radiculopathy". We request changes for use of this alternative term. The term "Disc Disease" has been replaced by "Degenerative disc disease" to make the nomenclature consistent with the standard nomenclature adopted by the American Back Society. We have made this change reluctantly because of the controversy surrounding the use of the term "disease" for erosion of a disc when the actual process is considered by many experts not to be a disease process.

Claims


It may be of interest that the Technology Assessment Division of the Medical Technologies Group, Ltd. (MTG), an independent health care assessment group, recently reviewed the literature relating to spinal decompression and concluded that "Coupled with modern imaging technology that recorded modifications in the extent of herniated discs with VAX-D therapy, no other non-interventional means of treating low back pain, mechanical or otherwise, has shown such promise." A cost comparison of use of the VAX-D™ compared to surgical procedures, such as laminectomy, discectomy or percutaneous discectomy revealed dramatic savings to the health care system. (MTG Newsletter August 1995/Vol.4 No. 8; MTG Newsletter September 1995/Vol.4 No. 9)

If there is any problem, please call our consultant as soon as possible:

Norman F. Estrin, Ph.D., RAC
President
ESTRIN CONSULTING GROUP, INC.
9169 Copenhaver Drive
Potomac, MD 20854
Phone: (301) 279-2899
FAX: (301) 294-0126

Thank you for your assistance.

Sincerely,


Allen E. Dyer, Ph.D., M.D.
President