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VAT-TECH INC.
38511 US HWY 19 NORTH
PALM HARBOR FL 34684
September 23, 1985

[Recipient Address]

Dear [Recipient Name]:

On September 23, 1984, [Sponsor Name], [Sponsor Title], on behalf of [Product Name], submitted the application for the [Application Type] for the product [Product Name] as required by [Regulatory Authority]. The application was received by the [Regulatory Authority] on September 23, 1984. The sponsor [Sponsor Identification] has been informed by [Regulatory Authority] of the status of the application.

Yours sincerely,

[Signature]

[Name]

[Title]

[Company Name]
1. Please provide information about the fire retardant properties of the cushion.

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

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

In the April 20, 1995 letter from Paul R. Beningo, 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 state our disagreement with this conclusion in the June 27, 1995 cover letter for our 510(k) submission since reference to "decompression" explains the mechanism of action for the intended use of "helping to remove low back pain." In addition, our original cleared submission for this device (K894435) uses the term "Discal Intervertebral Space," a term which has the identical meaning to "Deompress Intervertebral disc" or "Vertebral Axial Decompression." See the comparison table in TAB 3 of this submission. (For convenience, in this data 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.)

Vet-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 Vertebral Axial Decompression on Intradiscal Pressure by Gustav Ramen, 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.

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, these 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
"paradiscal radiculitis" has been used for K994455 and K961622. Since "radiculopathy" and "paradiscal radiculitis" are generally accepted as synonyms of peripheral radiculitis, Vax-Tech would like the freedom to use these terms as well. The term "paradiscal radiculitis" is being replaced in medical literature with the more accepted term, "paradiscal radiculopathy". We request clearance for use of this alternative term. The term "disc disease" has been replaced by "paradiscal 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.

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. 2; 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.
9109 Copakeaver Drive
Potomac, MD 20854
Phone: (301) 279-2399
FAX: (301) 279-0126

Thank you for your assistance.

Sincerely,

[Signature]

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