DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 28 1995

Allan E. Dyer, Ph.D., M.D.
President
VAT-TECH, Inc.
Connell Square
38511 U.S. Highway 19 North
Palm Harbor, Florida 34684

Re: K951622
VAX-D Therapeutic Table
Dated: September 28, 1995
Received: October 2, 1995

Dear Dr. Dyer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device because you did not completely respond to the deficiencies listed in our letter dated April 21, 1995 and requested during our phone conversation on September 13, 1995. Additionally, your responses to the deficiencies raised new issues. To complete the review of your submission, we require the additional information described below.

1. In your letter to FDA dated September 28, 1995 (most recent page 002), you state that the ground leakage tests were conducted according to standards set forth by the Canadian Standards Association (CSA) and that the maximum value of 500 microamps is the same as that in the UL standard. However, my information lists 100 microamps as the maximum allowable ground leakage current for patient care equipment according to UL 544. Please provide test results of ground leakage current that were performed according to standards recognized in the United States (UL 544 or UL 2601-1) and provide documentation from the standard supporting your test result if it is greater than the referenced 100 microamps.

2. In the same letter dated September 28, 1995, you state in item #3 (page 002) that only one claim, i.e., claims for decompression, was being questioned by FDA. It must be clarified that this decompression claim was identified in our April 21st letter as a basis for requiring that a new 510(k) be submitted for the VAX-D, and in no way infers that all other statements regarding this device in your labeling and promotional material were deemed appropriate.

The study you submitted was reviewed to determine whether it adequately addressed the issue of decompression. The data indicate that for each subject, a measurable decrease in intradiscal pressure was observed during the application of the VAX-D therapy. However, since the study included data on only 3 subjects (out of an initial 5), no statistical inference regarding decompression can be made on such a small sample. Additionally, we are concerned that using the terminology "decompression" could be misleading, since this is generally used to refer to surgical decompression of the spinal cord. FDA does acknowledge, however, that unweighting of the intervertebral disc and posterior facet joints can be achieved with your device due to the reduction in weightbearing forces placed on the vertebrae from the effects of traction and placement in a nonweightbearing position. Therefore, each time you refer to decompression you should define this as follows:

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

and state that all references to decompression in your labeling, promotional material, and other documentation will be modified accordingly.

3. Your September 28th letter also identifies (page 003) specific changes in terminology from your previously cleared 510(k) for the VAX-T to the current document for the VAX-D. FDA acknowledges that the earlier document was cleared containing the term "peripheral radiation [of pain]," and that the term "sciatica," having a similar meaning of referred pain due to the involvement of the sensory nerve fibers, can be a suitable replacement. However, the terms "neurological deficit" and "radiculopathy" are not appropriate substitutes since they may also include involvement to motor fibers of the mixed spinal nerve, and your previous document does not address damage to motor nerves. Therefore, you should indicate that your device will not be marketed using the terms neurological deficit, radiculopathy, or other similar terms. You may, however, use the term "radicular pain" since this infers that the radicular symptoms are only those of pain and do not contain a motor component. FDA also agrees that the term "degenerative disc disease" is commonly used to describe degenerative changes to the intervertebral disc and its sequelae, and therefore feels that its use is appropriate.

4. The comparison table of terminology between the VAX-T and VAX-D (pages 014-015) lists several terms requiring the following modifications:

   a. the phrase "Non-surgical decompression of the lumbar spine" should be qualified to include the language relating to unweighting due to distraction and positioning as described above in item #2;

   b. the term "significantly" should be removed since no statistical determination of significance could be determined from the small sample size in the submitted study. Additionally, it should be removed from all passages in the document, or a statement should be made indicating that you will delete this term from all device labeling, promotional material, and other documentation (those uses which I have been able to locate your 510(k) document are identified below, but others not so identified, should also be addressed);

   c. the phrase "Relieve pressure on vital structures of the lumbar spine" should be changed to "relieve pressure on structures that may be causing low back pain" since it is not possible to determine which structures of the spine are actually vital in regard to the onset of symptoms, and only those structures which may be causing low back pain need to be relieved;

   d. the phrase "through precisely controlled adjustments" should be changed to "distraction" since your device does not, in fact, provide precisely controlled adjustments, as would be the case with joint mobilization or manipulation where the technique can be applied to a specific spinal segment. Rather, your device simply provides generalized spinal traction affecting the entire length of the spine at the same time; and

   e. the term "neurological deficits" and "peripheral radiculopathy" should be deleted or modified as discussed above in item #3.

5. Please substantiate the claim (page 027) that "maintenance therapy, consisting of a treatment session on the VAX-T table at intervals of one or two weeks, offers a measure of protection against disabling exacerbations of their low back pain syndrome" by providing valid scientific data to show that it is, in fact, an effective means of preventing a recurrence, or

it should be deleted by either removing it from all passages in the document or including a statement that this claim will not be contained in your labeling, promotional material, or any other documentation for your device. Additionally, it has been my clinical experience that maintenance traction is not a generally accepted practice, and that once the patient's symptoms have resolved, a home program consisting of patient education, and range of motion, posture, and strengthening exercises is provided to protect against exacerbation of symptoms.

6. In your letter dated June 27, 1995 (previously submitted page 002), you question FDA's concern over use of the term "decompression." This is addressed above in item #2. (NOTE: all page numbers now refer to this previous submission).

7. The term "neurological deficits" (pages 024 and 025) should be deleted or modified, as discussed above in item #3.

8. The term "distraction" should be substituted for the term "decompression" in the phrase "...relaxation of muscle groups which is important in achieving effective decompression and mobilization of lumbar structures" (page 025) since the relaxation would allow the distraction to occur, which in turn, would cause the decompression. Should you decide to keep the term "decompression," it should be qualified as discussed above in item #2.

9. The claims of "...reduction of thecal sac displacement by protruding herniations" and "...reduce the extent of protrusion of subligamental herniated discs" should be substantiated with valid scientific evidence, as discussed above in item #2 for verifying the device's performance capabilities in achieving these new claims, or deleted by either removing them from all passages in the document or including a statement that these claims will not be contained in your labeling, promotional material, or any other documentation for your device.

10. The term "significantly" (pages 025 and 026) should be removed, as discussed above in item #4b.

11. In a discussion describing the effects of traction (page 026), you state that traction is performed "...for the purpose of relieving pressure on structures causing low back and sciatic pain." This phrase should be modified to read "...for the purpose of relieving pressure on structures that may be causing low back and sciatic pain"

when used to promote the therapeutic effect of your device, as discussed above in item #4c.

12. In another discussion regarding the effect of traction (page 027), you state that "foraminal stenosis" can respond to traction to "relieve nerve root compression long enough to allow nerve root swelling to decrease." Please provide valid scientific data to substantiate this effect relating to these specific anatomical structures or delete it by either removing it from all passages in the document or including a statement that this claim will not be contained in your labeling, promotional material, or any other documentation for your device.

13. The statement "...effective lumbar distraction and decompression has been an elusive goal until the inception of VAX-D Therapy" (page 027) infers that other traction devices are not able to provide effective lumbar distraction and decompression due to the distraction. Please provide valid scientific data to substantiate this claim or delete it by either removing it from all passages in the document or including a statement that this claim will not be contained in your labeling, promotional material, or any other documentation for your device.

14. The phrase "Decompression of the intervertebral disc during VAX-D Therapy exaggerates and increases this effect, producing a greater diffusion gradient" (page 028) when discussing the diffusion of nutrients into the disc across the vertebral endplates should be substantiated with valid scientific evidence or deleted by either removing it from all passages in the document or including a statement that this claim will not be contained in your labeling, promotional material, or any other documentation for your device.

15. The claim that "It is logical to assume that the diffusion and deposition of reparative collagen in the natural healing of annular tears and fissures would be enhanced during and post VAX-D treatment" (page 028) should be substantiated with valid scientific data or deleted by either removing it from all passages in the document or including a statement that this claim will not be contained in your labeling, promotional material, or any other documentation for your device.

16. The phrase that "...inflammation is decreased, and due to favorable nutrient gradients reparative beta collagen deposition is enhanced" (page 028) should be substantiated with valid scientific evidence or deleted

by either removing it from all passages in the document or including a statement that this claim will not be contained in your labeling, promotional material, or any other documentation for your device. In the same sentence, the relief of pain should be qualified to read "reduction of pain due to the effects of distraction."

17. As discussed in item #9 above, the claim for "reduction of thecal sac displacement by protruding herniations" (page 028) should be substantiated or deleted.

18. The claim for "...retraction of a lumbar hernia..." (page 028) should be substantiated with valid scientific evidence or deleted by either removing it from all passages in the document or including a statement that this claim will not be contained in your labeling, promotional material, or any other documentation for your device.

19. The claim "...lowers intradiscal pressures..." (page 028) should be qualified in the same manner as described for "decompression," as described above in item #2, to read:

"lowers intradiscal pressure due to distraction and positioning."

20. The claim "...to reduce the extent of protrusion of subligamental herniated discs" (page 028) should be substantiated with valid scientific evidence or deleted by either removing it from all passages in the document or including a statement that this claim will not be contained in your labeling, promotional material, or any other documentation for your device.

21. The claims that "...this process [protrusion and subsequent herniation] can be reversed by the application of vertebral axial decompression" and "...a retraction of the body of the nucleus pulposus to the center of the disc and interrupts the connection with the nuclear material that has penetrated the annular fibers" (page 030) should be substantiated with valid scientific evidence or deleted by either removing them from all passages in the document or including a statement that these claims will not be contained in your labeling, promotional material, or any other documentation for your device.

22. The claim that "...VAX-D therapy halts the hydraulic effect exerted by the nucleus..." (page 030) should be substantiated with valid scientific evidence or deleted by either removing it from all passages in the document

or including a statement that this claim will not be contained in your labeling, promotional material, or any other documentation for your device.

23. The need for "Daily repetition of therapy..." (page 030) should be substantiated as discussed above in item #5, and the claim that this daily treatment "...is essential in facilitating the reparative process and restoration of the integrity of the annular fibrous structure" (page 030) should be substantiated with valid scientific evidence or deleted by either removing it from all passages in the document or including a statement that this claim will not be contained in your labeling, promotional material, or any other documentation for your device.

24. The statement on page 031 that "The application of distraction tensions...by various traction modalities or devices would likely exert a similar effect on the annulus fibrosis...However unless this is coupled with lowering of the intradiscal pressures..." infers that your traction device is unique in being able to lower intradiscal pressure due to the effects of distraction. However, you have not substantiated the fact that other traction devices cannot lower intradiscal pressures, as discussed above in item #13. Therefore, you should substantiate this implied claim with valid scientific evidence or delete it by either removing it from all passages in the document or including a statement that this will not be contained in your labeling, promotional material, or any other documentation for your device.

25. The claims that decompression "...effect[s] the closure of the annular fibers" and that the "...effect of closure...would be largely negated by the fluid dynamics exerted by normally positive intradiscal pressures which would continue to press nuclear material into and through the annular tears" (page 031) should be substantiated with valid scientific evidence or deleted by either removing it from all passages in the document or including a statement that this claim will not be contained in your labeling, promotional material, or any other documentation for your device. Additionally, the following paragraph on page 031 states "...when decompression of the nucleus pulposus is achieved at the same time as the opposing angular annular fibers close with distraction of the vertebral bodies the combined effect facilitates reversal of the pathogenesis of herniation and enhances healing of the disc lesions" is confusing, and should also be substantiated or deleted as described earlier in this item.

26. The claim that VAX-D produces a "...favorable diffusion gradient across the endplate enhancing disc nutrition, [illegible] process" (page 036) should be substantiated with valid scientific evidence or deleted by either removing it from all passages in the document or including a statement that this claim will not be contained in your labeling, promotional material, or any other documentation for your device.

27. In item #I of your Substantial Equivalence documentation on page 087, the issue of decompression being a new intended use is again raised. This is address above in item #2.

28. You state on page 091 that "VAX-D...is a unique...therapy..." However, you have not proven that your device differs from other lumbar traction devices. This issue was previously discussed above in items #13 and #24, and again, this claim should be substantiated with valid scientific evidence or deleted by either removing it from all passages in the document or including a statement that this claim will not be contained in your labeling, promotional material, or any other documentation for your device.

29. The claim (page 091) that "VAX-D Therapy uses clinically proven principles to relieve pressure on vital structures of the lumbar spine and spinal nerves" should be modified to read:

"VAX-D Therapy relieves pressure on structures that may be causing low back pain"

since the study you submitted does not statistically prove that pressure was reduced (as discussed above in item #4b), the term "vital" is inappropriate (as discussed above in item #4c), and claims should be limited to reducing intradiscal pressure and not pressure reduction to other specific structures within the lumbar spine for which you have not provided valid scientific evidence in support of this claim.

30. You state on page 091 that "It [VAX-D] is not just aimed at treating symptoms but is designed to alleviate the underlying problems that cause low back pain..." However, there are numerous conditions that can cause low back pain, so this claim should be modified to indicate that the only problems for which this device is effective are those that are relieved by providing decompression due to the unweighting effects of traction and positioning, or valid scientific evidence should be submitted to substantiate other specific claims.

31. The claim "Clinical results have shown that VAX-D therapy provides some relief for almost all patients suffering from the common causes of low back pain and sciatica" (page 092) should be modified by removing the reference to "clinical results have shown" since no statistical inference can be made from the submitted study (as discussed above in items #4b and #29) and deleting the reference to "almost all patients" since you have not provided data so substantiate its effectiveness.

32. You again state on page 092 that "Some difficult cases may require an ongoing VAX-D maintenance program to continue pain free and flexible lifestyle." Please address this issue of maintenance therapy as described above in item #5.

33. The claim on page 094 that "Until now...methods of treatment [for low back pain] have been: bed rest, muscle relaxants and pain medications, manipulation and if all else failed, surgery" is incomplete. Other clinical modalities commonly used in rehabilitation such as, but not limited to ultrasound; superficial heat; electrical muscle stimulation; TENS; posture, mobility and strengthening exercises; supportive devices; and other traction devices are missing from your list of alternative therapies. The omission of other traction devices is especially puzzling since you have not provided data to demonstrate that your device is more effective than these other traction devices at either providing decompression (as discussed above in item #24) or for relieving pain. Therefore, you should add these additional treatment modalities to your list of alternative therapies, and when referring to other traction devices, you should not infer that VAX-D therapy differs from these devices unless substantiated with valid scientific evidence.

34. The claim "The Decompression Table (page 094) relieves pressure and factors causing pain through precisely controlled adjustments..." should be modified as stated above in item #2 relating to decompression caused by unweighting effects due to traction and positioning, item #4c regarding relief of pressure on structures that may be causing low back pain, and item #4d regarding the inability of your device to provide controlled adjustments.

35. You state (page 094) that "...most patients are able to return to normal levels of activity at work or recreation in as little as two weeks time." This claim should be substantiated with valid scientific evidence or deleted

by either removing it from all passages in the document or including a statement that this claim will not be contained in your labeling, promotional material, or any other documentation for your device.

36. The claim to "...distract the vertebral bodies and decompress the intervertebral discs and posterior facets of the lumbar spine" (page 097) should be modified as discussed above in item #2 by including the effects of unweighting due to traction and positioning in this statement.

37. You state that "On average, 10 to 15 sessions are usually required to attain remission of debilitating symptoms." However, you have not provided data to show that your device can actually result in the "remission of debilitating symptoms" or that it only requires "10 to 15 sessions" for this to occur. Therefore, you should substantiated these claims with valid scientific evidence or delete them by either removing them from all passages in the document or including a statement that these claims will not be contained in your labeling, promotional material, or any other documentation for your device.

38. The claim that "research...has established that significant decompression...is achieved with this equipment" is again made on page 098. However, the term "significant" should be substantiated or deleted as discussed above in item #4b.

39. The term "mobilization" is misleading and should be changed to "distraction" when you state that "Posterior facet syndromes...respond to mobilization achieved through VAX-D Therapy" (page 099) since distraction more accurately describes what your device actually does, whereas mobilization is generally understood to include movement applied in multiple planes of motion.

40. Please substantiate or delete your claims, as described above in item #35, that "...most patients...achieve remission of disabling symptoms sufficient to return to functional levels of activity with a course of therapy" and "Even the majority of patients...experience relief of pain and disability through the use of VAX-D Therapy" (page 099).

41. Please substantiate or delete the claim, as described above in item #5, that "...some [patients] may require a maintenance program..." (page 099).

42. You claim on page 099 that "Clinical trials have indicated that lumbar herniations are more likely to respond to decompression therapy when the protruding segment remains in communication with the nucleus." As stated above in item #29, you should remove the reference to "clinical trials" since you have not provided data from a clinical trial to support such a finding. Additionally, the second part of that claim suggesting that herniations are "more likely to respond to decompression therapy" should be substantiated with valid scientific evidence or deleted by either removing it from all passages in the document or including a statement that this claim will not be contained in your labeling, promotional material, or any other documentation for your device.

43. You infer on page 099 that your device is as effective as surgery when you state "The same principle [decompression therapy] appears to apply whether decompression is achieved via percutaneous discectomy or through a course of VAX-D Therapy." This claim should be substantiated with valid scientific evidence or deleted by either removing it from all passages in the document or including a statement that this claim will not be contained in your labeling, promotional material, or any other documentation for your device.

44. The claim that "Experience has shown that, generally, when patients recover on VAX-D Therapy, they remain in remission" (page 100) should be substantiated with valid scientific evidence or deleted by either removing it from all passages in the document or including a statement that this claim will not be contained in your labeling, promotional material, or any other documentation for your device.

45. Additional claims of maintenance therapy are made on page 100 when you state that "...maintenance therapy provides a measure of protection..." and "Regular treatment sessions on the VAX-D Table prove to keep patients free from problems." As stated above in item #5, these claims should be substantiated with valid scientific evidence or deleted by either removing it from all passages in the document or including a statement that this claim will not be contained in your labeling, promotional material, or any other documentation for your device.

46. You state that "VAX-D is the only therapeutic device that has been established through clinical research to...achieve non-surgical decompression of the lumbar spine" (page 101). However, you should delete the

reference to the clinical research since the study you submitted does not support the use of such a claim (as stated above in item #29) and, therefore, the reference that VAX-D is the only device that can achieve decompression should also be deleted since you have not shown that other traction devices cannot provide the same degree of decompression (as discussed above in items #13 and #24).

47. The term "neurological deficits" should be modified (as discussed above in item #3) in the claims "Clinical experience has shown that VAX-D provides relief from...neurological deficits" (page 101) and "Remission of Disabling Symptoms And Neurological Deficits..." (page 102).

48. The term "significantly" should be deleted from the claim on page 101 that states "Research...demonstrated that VAX-D Therapy significantly lowers intradiscal pressures of the lumbar spine" and from that on page 104 where you state "the results indicate that it is possible to lower pressures...to levels significantly below 0 mm Hg..." as discussed above in item #4b .

49. Please modify the term "decompress" in the phrases "...to decompress intervertebral lumbar discs" on page 102 and "...decompression of the intervertebral discs of the lumbar spine" on page 103 by qualifying that the decompression is the result of unweighting due to distraction and positioning (as discussed above in item #2).

50. In the SUMMARY OF SAFETY AND EFFECTIVENESS (page 103), you state that "The mechanism [decompression]...has been shown by clinical trials to be significant decompression..." As indicated above in item #29, the reference to clinical trials should be removed, and as stated above in item #4b, the term significant should be deleted, since the study does not statistically support either of these claims.

51. You also state in the SUMMARY OF SAFETY AND EFFECTIVENESS (page 104) that "The operating principles of the VAX-D...permit application of effective traction...without stimulating reflex muscle contractions..." This claim that reflex muscle contractions are not stimulated should be substantiated with valid scientific evidence or deleted by either removing it from all passages in the document or including a statement that this claim will not be contained in your labeling, promotional material, or any other documentation for your device.

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(f) and (h), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of this letter, please contact Mr. Elmar Einberg at (301) 594-1296. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Robert J. DeLuca

for Andrew Novick, M.A., P.T.
Restorative Devices Branch
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health