



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 20 1995

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 1995

Alan E. Dyer, Phm.B., B.Sc., Ph.D., M.D.
President
Vat-Tech, Inc.
38511 US 19, Connell Square
Palm Harbor, Florida 34684

APR 21 1995

Re: K951622
VAX-D Therapeutic Table
Dated: February 8, 1995
Received: March 2, 1995

Dear Dr. Dyer:

We have reviewed your current information describing the subject of K894435, the VAX-D Therapeutic Table (formerly the VAX-T Traction Table). Unlike the device described in the original Section 510(k) Premarket Notification (510(k)), the VAX-D table is computerized, which constitutes a significant change in design that could significantly affect the safety or effectiveness of the device. Additionally, claims for decompression of the intervertebral disc, as measured by the lowering of intradiscal pressures, represents a new intended use. As indicated in 21 CFR §807.81(a)(3), a premarket notification must be submitted when the device is about to be significantly changed or modified in design, components, methods of manufacture, or intended use. Therefore, we believe that the changes to your device as described above require the submission of a new 510(k). Accordingly, your information is now considered to be a new 510(k), document number K951622. We have completed an administrative review of your submission. Understandably, our review indicates that your 510(k) is administratively incomplete and we are placing your 510(k) on hold. We believe that basic information is necessary for us to begin our substantive review and to determine whether or not this device is substantially equivalent to devices marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (Act). Therefore, in order for us to begin the substantive review of your 510(k) submission we require the following information:

1. The truthful and accurate statement must be provided.
2. The device trade or proprietary name must be provided.

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3. The device common or classification name must be provided.
4. The establishment registration number of the owner or operator submitting the premarket notification submission must be provided (only applies if the establishment is registered).
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5. The class in which the device has been placed under Section 513 of the act must be provided; or if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified must be provided.
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6. The classification panel in which the device has been placed must be identified.
7. Any action taken to comply with the requirements of the act under Section 514 for performance standards must be described.
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8. Proposed labels, labeling, advertising and/or promotional materials, and specifications sufficient to describe the new device/modification, its intended use, and directions for use, as appropriate must be provided. If the device is a prescription device, the labeling must bear the caution statement as outlined in 21 CFR 801.109 (b)(1): "Caution: Federal law restricts this device to sale by or on the order of a physician [or dentist, if applicable]". If the device is reusable, instructions for maintenance, storing, cleaning, and disinfection/sterilization of the device must be included in the device labeling. Guidance on labeling issues is provided in ODE Bluebook Memo G91-1, "Device Labeling Guidance" dated March 8, 1991. A copy is available from the Division of Small Manufacturers Assistance, which may be contacted at the telephone number provided below.
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9. The Safe Medical Devices Act of 1990 (SMDA) requires that all persons submitting a premarket notification include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary); OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). For more information, see the FDA letter acknowledging receipt of your 510(k).

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10. The Safe Medical Devices Act of 1990 (SMDA) requires that any person who asserts that a device is substantially equivalent to a class III device to (1) certify that he/she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, and (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The summary must address safety and effectiveness issues related to the generic type of device as well as to the particular device under review. For more information, see the FDA letter acknowledging receipt of your 510(k).
11. Photographs of the device should be submitted to better document the physical description of each device included in the submission. The photographs should include internal/external, assembled/unassembled, and interchangeable parts of the device and should address the name and function of all parts of the device.
12. Engineering drawings of each device included in the submission must be submitted. These drawings should include the specifications (i.e., length, width, height, diameter, weights, power/electrical requirements, material, etc.) of the device with the applicable tolerances. All sizes, models, varieties, etc. of the device should be listed.
- If the device is sold in a set that includes accessories, these accessories must be identified. The same type of information as stated above must be supplied. Although the accessories themselves may be considered exempt, when used as part of a set with a higher class device, they are considered an accessory to the device and must be reviewed as such.
13. The legally marketed predicate device to which equivalence is claimed must be identified, and a copy of its labeling and a description of the device must be submitted. State whether the substantially equivalent device is a preamendment device or a device which has been cleared through the 510(k) process, providing the 510(k) document control number if known.

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14. A statement of the similarities and/or differences with the marketed device to which you are claiming equivalence must be provided. This statement should describe the similarities and differences in intended use, technology, and other important characteristics.
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15. You must provide a clear and organized comparison table, and accompanying discussion if necessary, which comprehensively describes the similarities and differences of the device in comparison with legally marketed products. If this 510(k) is for a modification to a marketed device, the modifications must be completely described. The information should include an identification of the device(s) to which substantial equivalence is claimed, as well as a comparison of intended use, design (including materials, specifications, energy used/delivered, etc.), labeling and performance.
16. Data to show the effects of your device modification on performance and safety and effectiveness must be provided. (It is helpful and time saving to supply information regarding the original device (i.e., drawings, specifications, etc.) rather than merely supplying the reference 510(k) number. If FDA must research the necessary information, a delay in the review process may result.)
17. Any action taken to comply with relevant voluntary performance standards must be described.
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18. Performance data are needed in order to determine equivalence for your device or device modification. Provide all bench, animal, and clinical data collected to demonstrate equivalence with respect to performance. This information should include the objectives of the studies conducted, the test methodology and/or protocol (including discussion as to the appropriateness of the tests selected), the study results, a discussion of the study results, and conclusions drawn from the studies. Performance testing should simulate clinical use of the device.
- Performance data must also be submitted for the device to which you claim equivalence so that an adequate comparative analysis may be conducted.
19. For patient-contacting devices, biocompatibility information and/or data for the device materials (including inks, dyes, markings, radiopaque

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materials, etc.) must be provided. Depending on the device and materials used, we may accept a certification from you that the exact same material and formulation is used in the device to which you claim equivalence. Therefore, if the materials are identical to the legally marketed device and are identically processed or sterilized, this should be explicitly stated. We may require biocompatibility test results to be submitted. Testing should be conducted on the final sterilized product in accordance with the "Tripartite Biocompatibility Guidance for Medical Devices," available from the Division of Small Manufacturers Assistance.

20. If a device is to be labeled "sterile", the method of sterilization, the sterility assurance level (SAL), and the method used to validate the sterilization cycle must be provided. In addition, if the method of sterilization is ethylene oxide (ETO), the maximum levels of ethylene oxide, ethylene chlorohydrin, and ethylene glycol residues which remain on the device following ETO sterilization must be identified. Residual levels of ethylene oxide, ethylene chlorohydrin, and ethylene glycol should comply with the appropriate maximum limits as proposed in the FEDERAL REGISTER, Vol. 43, p. 27482. If radiation sterilization is used, the dose delivered must be specified. A description of the manner, including materials, in which the device will be packaged in order to maintain device sterility must also be provided. If the device is to be labeled "pyrogen free" or "nonpyrogenic", the method used to make that determination must be described.

21. Software/firmware validation and verification and appropriate testing information must be submitted for all computer controlled devices. Hardware validation and verification may also be required for some devices. Further information regarding the required documentation for computer controlled devices can be found in the Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review which can be obtained from the Division of Small Manufacturers Assistance.

22. If your device is a kit, all components of the kit must be identified and the following certification must be provided:

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I certify that the following components of my kit are either (1) legally marketed pre-amendment devices, (2) exempt from premarket notification (consistent with the exemption criteria described in the classification regulation(s) and the limitations of exemptions from Section 510(k) of the act (e.g., 862.9), or (3) have been found to be substantially equivalent through the premarket notification process for the use(s) for which the kit is to be intended (i.e., I am not claiming or causing a new use for the component(s)).

I further certify that these components are not purchased in "bulk", but are purchased in finished form, i.e., they are packaged, labeled, etc., consistent with their pre-amendments, exemption, or premarket notification criteria and status.

If you cannot make the above referenced certification statement (first paragraph) for each component of your kit, you must itemize the components without a pre-amendments, exemption, or premarket notification status. In this case we will continue our premarket notification review of these components of your kit.

If you cannot make the above referenced certification statement (second paragraph) for each component of your kit, you must itemize these components, state whether they are pre-amendments, exempt, or have been found substantially equivalent through the premarket notification process and describe how you further process them (e.g., sterilize).

If your kit contains examination gloves which are purchased in bulk, your submission must contain either a certification or data demonstrating that the final finished sterile examination gloves in the kit meet the ASTM standards for rubber examination gloves (ASTM D 3578-77) and pass the FDA 1000 milliliter water leak test in accordance with the sample plan and test method published in the FEDERAL REGISTER, Vol. 55, p. 51254-51258.

If the kit contains sutures, provide evidence that the sterilant does not contact the sutures during the sterilization process. In addition, it should be noted that a change in the labeling, packaging,

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method of sterilization, or supplier of the sutures in your kit requires the submission of a new 510(k).

If your kit contains components which are subject to regulation as drugs, a substantially equivalent determination will not apply to the drug components of the kit. For additional information on applicable agency requirements for marketing the drug component(s) in the kit, contact the Center for Drug Evaluation and Research's Division of Drug Labeling Compliance at (301) 295-8063.

23. Information identified in the enclosed guidance document must be provided.
24. Identify another predicate device for your product. We are unable to document that the device which you identified in your submission as a predicate device has been cleared by FDA for marketing. Alternately, provide evidence that the predicate device that you identified was on the market in the U.S. prior to May 28, 1976.
25. A table of contents, listing of tabs and appendices, and appropriate pagination for your premarket notification must be provided.

The additional information should be submitted in duplicate, referencing the 510(X) number above to:

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

Please note that since your 510(K) submission has not been substantively reviewed, additional information may be required during the review process and the file may again be placed on hold. You may not market this device until you have provided adequate information as 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 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 exemptions (IDE) regulations (21 CFR part 812).

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If the requested information 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.

If you have any questions concerning the contents of this letter, please contact Mr. Andy Novick at (301) 594-1296. If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll free number, in the U.S., (800) 638-2041.

Sincerely yours,

Paul R. Beninger, M.D.

Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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