DEC 2 8 2005

K053503

FDA 510(k) _____

VAX-D GENESIS SYSTEM

SUMMARY OF SAFETY AND EFFECTIVENESS

1. **SPONSOR IDENTIFICATION**

VAX-D MEDICAL TECHNOLOGIES LLC.
310 Mears Blvd
Oldsmar, FL 34677

Telephone: (813) 343-5000
Facsimile: (813) 343-5005

2. **SPONSOR ESTABLISHMENT REGISTRATION NUMBER(s):**

1058809
Owner ID No. 9031244

3. **OFFICIAL CONTACT PERSON**

Dr. Lawrence A. Dyer
Telephone: (813) 343-5000
Facsimile: (813) 343-5005

4. **DATE OF PREPARATION OF SUMMARY:** October 21, 2005

5. **DEVICE INFORMATION**

A.	DEVICE PROPRIETORY NAME:	VAX-D Genesis System
B.	CLASS AND REFERENCE:	Class II (21CFR Section 890.5900)
C.	PRODUCT CODE:	89 ITH
D	PANEL CODE:	87OR

6. **PREDICATE DEVICE:** VAX-D Therapeutic Table (K951622)

7. **DEVICE DESCRIPTION**

The VAX-D Genesis System is designed to apply distraction tensions to the patient's lumbar spine in order to non-surgically decompress the spine and intervertebral discs. The patient is fitted with pelvic harness and lies on the table; the upper body is positioned on the stationary portion of the table and is restrained by the patient holding on to adjustable handgrips, or by the use of a passive shoulder restraint. The table is a split table design, whereby distraction tensions are applied to the patient through a pelvic harness attached to a tensionometer and by the separation of the movable part of the table. The system is designed to apply tensions to the lumbar spine in a smooth logarithmic time/force curve that allows trunk and paraspinal muscles to relax. The system provides automated or variable timed distraction-relaxation cycles. For safety the patient holds on to handgrips which can

be released at any time to end the session and restore full relaxation. The patient may choose to use a passive shoulder restraint that utilizes a patient 'quick release' buckle, or they may simply raise their arms to release. Distraction tensions and rates are continuously monitored and measured by the tensionometer attached to the pelvic belt, and the output is monitored by a computer system which continuously processes the data and adjusts the tension to produce a patented 'logarithmic' decompression curve. The chart recording produced is a permanent record of the treatment parameters which becomes part of the patient's chart.

8. INTENDED USE

The VAX-D Genesis System is designed to relieve pressure on structures that may be causing low back pain and sciatica. It relieves the pain associated with herniated discs, degenerative disc disease, posterior facet syndrome and radicular pain. Intervertebral disc decompression is achieved non-surgically through the application of logarithmic distraction tensions applied to the patient according to the VAX-D protocol.

9. INDICATIONS FOR USE

This therapy provides a primary treatment modality for the management of pain and disability for patients suffering with low back pain. It has been found to provide relief in a variety of conditions involving anatomical dysfunctions of the lumbar spine that generate localized low back pain as well as peripheral radiation, including patients with protruding or herniated intervertebral discs as well as those with acute facet problems and sciatica.

10. TECHNOLOGICAL CHARACTERISTICS

The VAX-D Genesis System is essentially the same product as the predicate device, the VAX-D Therapeutic Table (K951622). VAX-D Medical Technologies has made some modifications to the appearance and components used in the VAX-D Therapeutic Table to provide more accurate application of tension, and to provide for the storage of patient data. Each of these changes was evaluated by VAX-D Medical Technologies and found not to impact the safety and effectiveness of this device.

11. SUMMARY OF SAFETY AND EFFECTIVENESS

The operating principles of the VAX-D Genesis System permit the application of accurately controlled distraction tensions to the lumbar spine in order to decompress the intervertebral discs and spinal structures. The important basic parameters contributing to the safety and effectiveness of the device include the smooth and gentle logarithmically applied distraction tensions, the smooth logarithmic release rate of tensions and relaxation cycles, the cyclic periodicity, the upper limit on distraction tensions of one-hundred pounds, and in addition, the positioning of the patient and the means of fixing the upper body. An important safety factor is that patients can immediately release all tensions by simply releasing the hand-grips or by using the quick release buckle if the passive shoulder restraint is used. VAX-D therapy has been in clinical use since 1989 and has been the

subject of multiple clinical studies examining its effectiveness and mechanisms of action. VAX-D therapy Medical Technologies maintains contact with the clinics administering the therapy, and over the past twelve years, not a single MDR report of injury has been filed, which reflects the inherent safety of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 8 2005

VAD-D Medical Technology Services, LLC
% Mark Job
Responsible Third Party
Regulatory Technology Services, LLC
1394 25th Street N.W.
Buffalo, Minnesota 55313

Re: K053503
Trade/Device Name: VAX-D Genesis System
Regulation Number: 21 CFR 890.5900
Regulation Name: Power traction equipment
Regulatory Class: II
Product Code: ITH
Dated: December 13, 2005
Received: December 16, 2005

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

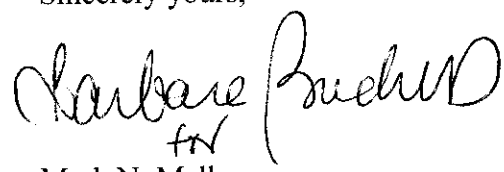
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 443 6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: VAX-D Genesis System

Indications for Use:

This therapy provides a primary treatment modality for the management of pain and disability for patients suffering with incapacitating low back pain and sciatica. It is designed to apply decompressive forces to compressive and degenerative injuries of the spine. It has been found to provide relief of pain and symptoms associated with herniated discs, bulging or protruding intervertebral discs, degenerative disc disease, posterior facet syndrome and sciatica.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buch MD

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K053503