K071347

OCT 5 ˇ 2007

VAX-D GENESIS G2 510(k) _____

SUMMARY OF SAFETY AND EFFECTIVENESS

1. **SPONSOR IDENTIFICATION**

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

OCT 5 ˇ 2007

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:** April 30, 2007

5. **DEVICE INFORMATION**

A. DEVICE PROPRIETORY NAME: ***VAX-D Genesis G2 - Dynamic Logarithmic Spinal Decompression System***
B. CLASS AND REFERENCE: Class II (21CFR Section 890.5900)
C. PRODUCT CODE: 89 ITH
D PANEL CODE: 87OR

6. **PREDICATE DEVICE(s):**

VAX-D Genesis System	K053503
VAX-D Therapeutic Table	K951622
3D Activetrac	K001712
Henley Tru-Trac 401	K844385

7. **DEVICE DESCRIPTION**

The VAX-D Genesis G2 is designed to apply distraction tensions to the patient's lumbar and cervical spine in order to non-surgically decompress the spine and intervertebral discs. Disc decompression is defined as unloading due to distraction and positioning. For lumbar treatment 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 harness attached to a tensionometer and by the separation of the movable part of the table. The tensionometer can be programmed to move synchronously in a horizontal and vertical plane in order to

apply tension in a logarithmic time/force progression that is designed to follow the curvature of the spine.

The system is designed to apply tensions to the 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 use the handheld patient safety switch to stop the treatment. For cervical treatment the tensionometer applies tension to the cervical spine through a cervical harness. Distraction tensions and rates are continuously monitored and measured by the tensionometer, and the output is monitored by a computer system which continuously processes the data and adjusts the tension to produce a patented 'logarithmic' 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 G2 Dynamic Logarithmic Spinal Decompression System* is designed to relieve pressure on structures that may be causing low back pain, sciatica and neck pain. It relieves the pain associated with herniated discs, degenerative disc disease, posterior facet syndrome and radicular pain. This 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 spinal pain. It has been found to provide relief in a variety of conditions involving anatomical dysfunctions of the spine that generate localized 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 G2 incorporates the various principles and working characteristics of the predicate devices, VAX-D Genesis System K053503, the VAX-D Therapeutic Table K951622, the 3D Activetrac K001712 and the Henley Tru-Trac 401 K844385. VAX-D Medical Technologies has made some modifications to the appearance and components used in the VAX-D Genesis System which provides for a control arm instead of a control console; to provide for 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. The Tru-Trac 401 has been in use for more than ten years for traction of the cervical spine and we have no evidence of an MDR report being filed by the manufacturer.

11. SUMMARY OF SAFETY AND EFFECTIVENESS

The operating principles of the VAX-D Genesis G2 permit the application of accurately controlled distraction tensions to the lumbar and cervical spine in order to decompress the intervertebral

discs and spinal structures. Disc decompression is defined as unloading due to distraction and positioning. 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 limits on distraction tensions, and in addition, the positioning of the patient and the means of fixing the upper body. The important safety factors are that patients can immediately release all tensions by simply releasing the handgrips, by using the quick release buckle on the passive shoulder restraint or through the patient handheld safety switch.

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 fourteen 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

Vax-D Medical Technologies USA
% Regulatory Technology Services
Mr. Mark Job
1394 25th Street
Buffalo, MN 55313

OCT 5 2007

Re: K071347
Trade/Device Name: VAX-D Genesis G2-Dynamic Logarithmic Spinal Decompression System
Regulation Number: 21 CFR 890.5900
Regulation Name: Power traction equipment
Regulatory Class: II
Product Code: ITH
Dated: September 19, 2007
Received: September 21, 2007

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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
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 : _____

Device Name: VAX-D Genesis G2

Indications for Use:

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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)

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

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