MAY - 1 2001

K010292

SECTION VIII

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Description:

Device Trade Name:	DRX 2000
Common Name:	Traction Equipment
Classification Name:	Power Traction Equipment
Class and Reference	Class II (21 CFR Section 890.5900)
Product Code:	89ITH
Panel Code:	87ORS

Predicate Devices:

K844385 Tru-Trac 401 Traction – Henley International
K951622 VAX-D® Therapeutic Table – Vat-Tech, Inc.

Proposed Intended Use

The DRX 2000 provides a program of treatments for relief from pain for those patients suffering with low back pain. Each treatment consists of a physician prescribed treatment period on the DRX 2000 and is designed to provide static, intermittent, and cycling distraction forces to relieve pressures on structures that may be causing low back pain. It relieves pain associated with herniated discs, protruding discs, degenerative disc disease, posterior facet syndrome, and sciatica. It achieves these effects through decompression of intervertebral discs, that is, unloading due to distraction and positioning.

Technological and Clinical Application Characteristics

The DRX 2000 incorporates various principles and working characteristics of the predicate devices, Tru-Trac 401 Traction Device (K844385) and the VAX-D Therapeutic Table (K951622). The incorporating of the traction device and a flat surface type powered bed, whilst giving a new overall appearance to the apparatus, has not impacted on or changed the safety of effectiveness of the devices. The Tru-Trac 401 has been in use in this country for more than ten years and we have no evidence of a MDR report being filed by the manufacturer nor have we been made aware of any events or conditions effecting the operation of this equipment. Clinical trials carried out by VAX-D endorse the principle of decompression and similar studies using similar technology have reported the same results. (Please see the Appendices).

Summary of Key Descriptive Elements:

The key elements to the DRX 2000 are as follows:

1. The bed is a stand on/stand off tilt type bed that allows the fully clothed patient to step onto a footrest while it is in near vertical position. The bed and patient can then be slowly lowered to the horizontal treatment position using a remote controller hand held by the practitioner.
2. Once in the horizontal position the bed can be raised or lowered to the practitioner's preferred treatment height via the same hand held remote controller.
3. The bed is split into two cushions, each slide able in the horizontal plane only on low friction runners and each being able to be locked independently.
4. Distraction tensions are applied to the patient via a pelvic harness while the upper body of the patient is anchored to the locked upper cushion via a chest harness. The lower cushion, which is unlocked and on which the patient's lower trunk is rested, is able to slide easily thus reducing almost completely any frictional movement between patient and bed cushion when distraction tensions are applied, this concentrates virtually all the forces to the affected part of the lumbar spine.
5. The traction unit is mounted to a vertical movable platform incorporated into a tower at the foot end of the bed. This enables the distraction tensions to be applied at differing angles to the patient (between 0 and 30 degrees).
6. The traction unit is programmed and controlled from a control panel fitted into the tower to give static or intermittent distraction.
7. The minimum and maximum distraction settings are 0-200 lbs..
8. Treatment parameters i.e. tensions and time are continuously monitored and shown by LCD readout at the time of treatment set up and during treatment.
9. At the conclusion of treatment time, tension always returns to zero.
10. A cassette player, which is incorporated in a separate section of the control panel, and wireless headphones provide comfort and relaxation to the patient.
11. There is instantaneous release of all tensions if the patient pushes the button on the hand held Patient Safety Switch, or the Stop Button on the control panel has been pushed by the practitioner.
12. The DRX 2000 will not operate if the Patient Safety Switch is not working properly or has not been tested prior to each treatment.
13. The treatment cannot be restarted when a patient activates the Patient Safety Switch or the Stop Button has been pushed during treatment unless all treatment parameters are manually re-entered into the controller.

Summary of Safety Features

The more important safety features of the DRX 2000 include:

1. The activation of pillars and actuators for the bed are via a 24-volt electrical circuit.
2. The control circuitry for the distraction unit including the power supply to the Patient Safety Switch is a maximum 24 volts.
3. The patient is automatically reclined to the treatment position rather than climbing onto the treatment bed.
4. There is instantaneous release of all tensions when the button on the hand held Patient Safety Switch is depressed, the Stop Button is pressed on the control panel, or when electrical current is interrupted. The treatment program cannot be automatically restarted when any of those items in no. "5" have occurred without the full treatment parameters being manually re-entered into the control panel.
5. All treatment parameters must be manually entered each time a treatment occurs.
6. There is a limited vertical movement of the traction box.
7. There is a permanent, visible means of indication of the angle of distraction pull.
8. There is an audible warning signal when the unit is first turned on, when the treatment is completed, when the Patient Safety Switch is tested, when the Patient Safety Switch is activated during treatment, and when the entered treatment distraction parameter exceeds 39 lbs. force of tension.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2001

Axiom Worldwide, Inc.
Jim Gibson
President and CEO
3830 Gunn Highway
Tampa, Florida 33624

Re: K010292
Trade/Device Name: DRX 2000™
Regulation Number: 890.5900
Regulatory Class: II
Product Code: ITH
Dated: January 30, 2001
Received: January 31, 2001

Dear Mr. Gibson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010292

Device Name: **DRX 2000**

Indications For Use:

Intended Use

The DRX 2000 provides a program of treatments for relief from pain for those patients suffering with low back pain. Each treatment consists of a physician prescribed treatment period on the DRX 2000 and is designed to provide static, intermittent, and cycling distraction forces to relieve pressures on structures that may be causing low back pain. It relieves pain associated with herniated discs, protruding discs, degenerative disc disease, posterior facet syndrome, and sciatica. It achieves these effects through decompression of intervertebral discs, that is, unloading due to distraction and positioning.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

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

510(k) Number K010292

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)