K060735

MAY 26 2006

SECTION VIII

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. **Sponsor Identification**

Axiom Worldwide, Inc.
9423 Corporate Lake Dr
Tampa, FL 33634
Telephone: (813) 249-6444
Facsimile: (813) 249-6445

2. **Sponsor Establishment Registration Number**

Establishment Registration Number: 3004378341
Owner / Operator Number: 9044586

3. **Official Contact Person**

Jim Gibson
Telephone: (813) 249-6444
Facsimile: (813) 249-6445

4. **Device Information**

Device Trade Name:	DRX9000 True Non-Surgical Spinal Decompression System
Common Name:	Traction Equipment
Classification Name:	Power Traction Equipment
Class and Reference	Class II (21 CFR Section 890.5900)
Product Code:	89 ITH
Panel Code:	87 ORS

5. **Predicate Devices**

K022602 DRX3000 – Axiom Worldwide
K053503 VAX-D Genesis System – VAX-D Medical Technologies

6. **Device Description**

The DRX9000 True Non-Surgical Spinal Decompression System provides accurately controlled tensions designed to relax and confuse paraspinal muscles and allow distractive forces to decompress intervertebral spinal disc space. The user interface provided by the treatment computer constantly updates a servo-amplifier controlling a servo-motor to immediately and safely apply forces as determined by qualified healthcare personnel. Load-cell feedback is utilized to further verify and adjust tensile forces, allowing for variations in patient posture and outside forces such that continuous and smooth tension is experienced by the patient. The patient safety switch is held by the patient who at anytime and for any reason may quickly

pause any tensile forces. This patient safety switch is monitored and executed by two redundant systems. Integral to effective spinal decompression and included in the device are continuous load-cell tensile feedback into the treatment computer, dedicated and matched servo-amplifier and servo-motor, smoothly modulated cyclic tension application (high and low tension plateaus transitioned into via non-linear tension change), two segment (upper and lower) textile patient harness, patient safety switch, and free-floating lower body mattress. The free-floating lower body mattress allows the interdiscal segments of the lumbar spine to decompress at their own rate. As tension is cycled, the lower body can extend independent of the upper body which is held in place via an upper body textile patient harness. The treatment bed and textile harness allow the patient to relax completely and require no conscious exertion on the part of the patient. Total patient relaxation encourages paraspinal muscle relaxation from both a physical and psychological standpoint and is a key to spinal decompression.

7. **Intended Use**

The DRX9000 True Decompression 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 Axiom protocol.

8. **Indications for Use**

The DRX9000 True Non-Surgical Spinal Decompression System 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 spinal 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.

9. **Technological Characteristics**

The Axiom Worldwide DRX9000 True Non-Surgical Spinal Decompression System is essentially the same product as the predicate device (DRX3000). Axiom Worldwide has made some modifications to the appearance and components used in the Axiom Worldwide DRX3000 to provide more accurate application of tension. Each of these changes were evaluated by Axiom Worldwide and found not to impact the safety and effectiveness of this device.

10. **Summary of Safety and Effectiveness**

The DRX9000 True Non-Surgical Spinal Decompression System provides accurately controlled tensions designed to relax and confuse paraspinal muscles and allow distractive forces to decompress intervertebral spinal disc space. Integral to

effective spinal decompression and included in the device are continuous load-cell tensile feedback into the treatment computer, dedicated and matched servo-amplifier and servo-motor, smoothly modulated cyclic tension application (high and low tension plateaus transitioned into via non-linear tension change), two segment (upper and lower) textile patient harness, patient safety switch, and free-floating lower body mattress. An important safety feature is that patients hold a patient safety switch to allow at anytime the pausing of any tensile forces. Axiom Worldwide therapy has been in clinical use since 2002 and has been the subject of clinical studies examining its effectiveness. Axiom Worldwide 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

MAY 26 2006

Axiom Worldwide, Inc.
% TÜV Rheinland of North America, Inc.
Mr. Tamas Borsai
Program Manager
12 Commerce Road
Newtown, Connecticut 06470

Re: K060735
Trade/Device Name: DRX9000 True Non-Surgical Spinal Decompression System
Regulation Number: 21 CFR 890.5900
Regulation Name: Power traction equipment
Regulatory Class: Class II
Product Code: ITH
Dated: May 9, 2006
Received: May 11, 2006

Dear Mr. Borsai:

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,

for 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 (if known):

Device Name:

Indications For Use:

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K060735

Device Name: DRX9000 True Non-Surgical Spinal Decompression System

INDICATIONS FOR USE

The DRX9000 True Non-Surgical Spinal Decompression System 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 spinal 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) (21 CFR 801 Subpart C)

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

Herbert Lerner MD

(Division Sign-Off)

Division of General, Restorative and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K060735