SECTION VIII

JAN 23 2003

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Description:

Device Trade Name:	DRX3000
Common Name:	Traction Equipment
Classification Name:	Power Traction Equipment
Class and Reference	Class II (21 CFR Section 890.5900)
Product Code:	89 ITH

Predicate Devices:

K010292 DRX 2000 - Axiom WorldWide
K844385 Tru-Trac 401 Traction – Henley International
K951622 VAX-D® Therapeutic Table – Vat-Tech, Inc.

Proposed Intended Use

The DRX3000 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 DRX3000 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 DRX3000 incorporates various principles and working characteristics of the predicate devices, the DRX 2000 Axiom's proprietary predicate device (K010292), the 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).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. James J. Gibson, Jr.
President & CEO
Axiom USA, Inc.
3830 Gunn Highway
Tampa, Florida 33624

JAN 23 2003

Re: K022602
Trade/Device Name: DRX3000™
Regulation Number: 21 CFR 890.5900
Regulation Name: Power traction equipment
Regulatory Class: Class II
Product Code: ITH
Dated: November 12, 2002
Received: November 13, 2002

Dear Mr. Gibson:

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.

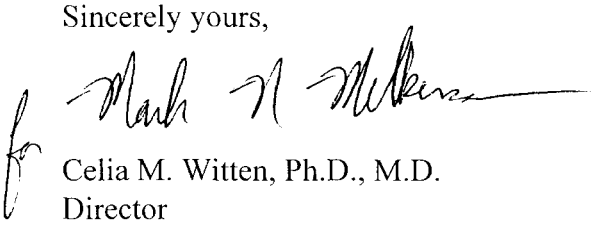
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,



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

Axiom USA, Inc.
DRX3000™ - 510(k) Notification Submission

510(k) Number (if known): K022602

Device Name: DRX3000

Indications For Use:

Intended Use

The DRX3000 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 DRX3000 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

for Mark N. Milhern

(Division Sign-Off)

D[illegible]

and Neurological Devices

510(k) Number K022602