510(k) Summary of Safety and Effectiveness

Company Name:

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Date of Summary: January 28, 2005
Trade Name: SpineMED® S200B/S200C
Common Name: Powered Traction Equipment
Classification Name: Powered Traction Equipment
Class and Reference: Class II (21 CFR Section 890.5900)
Product Code: ITH
Panel Code: 87ORS
Regulation Number: 890.5900

Predicate Devices:

We are making the claim that the SpineMED® S200B/S200C is substantial equivalent to the predicated devices listed in the chart below.

LEGALLY MARKETED PREDICATE DEVICE	MANUFACTURE NAME	REGULATORY CLASS AND PRODUCT CODE	510(K) REGISTRATION NUMBER
3D Activetrac	The Saunders Group-	Class II/ITH	K001712
DRX5000	AXIOM USA Inc	Class II/ITH	K023160

The rationale of declaring the SpineMED S200B/C is substantial equivalent to the above 2 predicate devices are based on the following:

- ✓ Same Indications for use: All systems provide treatments for relief of pain associated with low back pain, neck pain and sciatica. The treatment consists of a physician prescribed treatment period in which static, intermittent, and cycling distraction forces are applied to relieve pressures on structures that are causing low back pain, neck pain and sciatica.
- ✓ Similar key design technical characteristics- Multi-function traction table designed to applied distraction forces and controlled by a computer console.
- ✓ Same/similar components for treatment and measurement.
- ✓ Similar size, power source, and performance

Device Description:

The SpineMED® is a multi-function Hi-Lo traction table designed to apply distraction forces to a patient's spine (Lumbar and Cervical). The powered Hi-Lo adjustments of the table surface height are designed to provide easier loading and unloading of the patient on and off the table. Maximum lift capacity and weight bearing capacity is 400lbs.

The patient lies in a supine position on the table with the legs supported with a removable knee bolster. For increased comfort during the distraction, and to provide relaxed distraction of paraspinal tissue, an infrared heating pad is incorporated into the table surface directly beneath the lumbar area. This 12 Vdc infrared element can be turned on or off during the treatment.

The upper body is restrained through a chest harness, which is then attached to the fixed upper section of the table with a mechanical safety release buckle. The lower body is restrained to the moveable lower section of the table though pelvic restraints that are designed to capture and secure the patient's iliac crest.

The removable pelvic restraints are supplied in two sizes, to accommodate different patient sizes, and are removed from the table for patient loading and unloading. The pelvic restraints are adjusted laterally to fit patient's widths through an acme screw assembly incorporated into the tilting lower section. Turn handles are attached to the acme screw on either side of the table, and allow for uniform movement of the pelvic restraints together and apart, for an operator controlled comfortable fitting to the patient.

The table is a split-table design, whereby distraction tensions are applied to the patient through the pelvic restraints during the separation of the table. The lower table section is powered by a computer-controlled 24 VDC actuator, which separates the two table sections to a maximum of eight inches. The distraction tensions and rates are continuously monitored and measured by load cells, which transfer this information to the integrated computer. A similar setting is present for the cervical setup. On top half of the split-table a cervical unit is attached, which applies tension to the high end of the spine. This unit is controlled by a 24 VDC actuator, which is controlled by the main

computer. Information from the actuator is sent to the computer which displays the tension applied during the cervical treatment.

An incorporated battery backup system provides adequate system power to continue full operation of the SpineMED® in event of power failure, allowing safe continuation of treatment session. For safety, the patient is provided with an electrical hand-held patient safety switch, which when depressed, immediately interrupts the treatment session and gradually eliminates the application of force to zero under a controlled rate. A secondary safety device incorporates a mechanically-operated buckle for the upper harness, which the patient can control its release by simply pulling a switch integrated in the side of the table. The switch releases all distraction forces to the patient.

All treatment parameters and data are captured on the LCD screen and can be printed out to a printer and are stored electronically in the database. There are no new potential flammable materials used in the S200B/C. All material remain the same as the original 510k submission of the S100A(K030060).

Indications for Use:

The SpineMED® System provides a program of treatments for relief from pain for those patients suffering with low back pain, neck pain or sciatica. Each treatment session consists of a physician prescribed treatment period on the SpineMED™ and is designed to provide static, intermittent, and cycling distraction forces to relieve pressures on structures that may be causing low back pain, neck pain or sciatica. It relieves pain associated with herniated discs, bulging or 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.

Summary of Performance Testing:

A risk analysis identifying potential hazards and documenting mitigations of the hazards has been developed and applied as part of the SpineMED S200B/C product development cycle. The risk analysis is based on EN 1441/ISO14971 - Risk Analysis for Medical Devices.

Testing was performed to validate the functional performance of the SpineMED system. In particular, specific performance testing of the software was performed to show that the performance was met. Testing is in accordance to the 'SpineMED Test Procedure Checklist' prior to any production units shipped to the end customer.

The SpineMED S200B/C has been subjected to performance testing to applicable safety, electrical, mechanical, EMC standards. The SpineMED S200B/C system has been evaluated and has passed all mechanical and electrical safety according to CSA International. Standards that were investigated are: IEC 60601-1, UL 60601-1 and CAN/CSA C22.2No.601.1-M90 certified

Conclusion:

As stated above, CERT Health Sciences's conclusion is that the SpineMED S200B/C is safe and effective and complies with the appropriate medical standards and is substantially equivalent to the above identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2005

CERT HEALTH SCIENCES, LLC
c/o Mr. Tamas Borsai
TUV Rheinland of North America, Inc.
12 Commerce Road
Newton, Connecticut 06470

Re: K051013
Trade/Device Name: SpineMED® S200B/S200C
Regulation Number: 21 CFR 890.5900
Regulation Name: Power traction equipment
Regulatory Class: II
Product Code: ITH
Dated: April 14, 2005
Received: April 21, 2005

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,

Miriam C. Provost, Ph.D.
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: SpineMED® S200B/S200C

Indications For Use:

The SpineMED® System provides a program of treatments for relief from pain for those patients suffering with low back pain, neck pain or sciatica. Each treatment session consists of a physician prescribed treatment period on the SpineMED™ and is designed to provide static, intermittent, and cycling distraction forces to relieve pressures on structures that may be causing low back pain, neck pain or sciatica. It relieves pain associated with herniated discs, bulging or 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.

Prescription Use __X_____ 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)

[illegible]
[illegible], General, Restorative
and Neurological Devices

K051013