K043239

DEC 22 2004

Trade Name:	Healthstar Elite
Common Name:	Powered Traction Equipment
Classification Name & Code:	Powered Traction Equipment Class II (21 CFR Section 890.5900) ITH
Classification Advisory Committee	Physical Medicine
Reason:	It is a new device
Predicate Device:	DRS System Professional Distribution Systems, Inc. 510(k): K981822 SpineMED Cert Health Sciences, LLC 510(k): K030060

Description:

The Healthstar Elite is a multifunction elevation traction table designed to apply distraction forces to a patient's spine. The powered elevation adjustments of the table's surface height are designed to provide easier loading and unloading of the patient on and off the table.

The patient lies in a supine position on the table with either the knees bent or legs supported on an adjustable height stool creating a 90-degree bend between the calves and hamstrings. This position helps to provide comfort during distraction and to provide relaxation to the Para spine tissue during distraction.

The upper body is restrained through a chest harness, which is attached underneath the rib cage. The harness is attached to a metal spreader bar and web strap, then attached through a cam-type buckle assembly. The lower body is restrained to the moveable lower section of the table through a flexible pelvic restraint. This restraint is fixed to the table's lower moveable section. Each side of the restraint can be moved in and out width wise by pushing a lever and having a stud engage into one of three numbered holes,

depending on the size of the patient. The flexible restraint is designed to capture and secure the patients iliac crest.

The Healthstar Elite consists of two components:
1. The elevation table with traction capabilities.
2. An attachable control panel, which can be inserted into either side of the table.

The elevation table is controlled by a 24-volt actuator and is elevated by pushing a hand control with built in arrows indications (no label required).

The control panel allows the operator to select one of eight predetermined programs of distraction, time of treatment, pounds of distraction, and pelvic tilt angle.

Technological Characteristics

Healthstar Elite incorporates various principles and working characteristics of the predicate devices, SpineMED (K030060), DRS System (K981822) and SPINA System (K002260). The Healthstar Elite employs a unique method of restraining the patient's body to the table surface, which has not impacted on, or changed the safety or effectiveness of the device.

Summary of Safety and Effectiveness

The operating principles of the Healthstar Elite permit the safe application of effective distraction tensions of the lumbar spine. The patient is provided with a handheld cut off switch, which, when depressed, will interrupt the treatment and will gradually eliminate the application of force to zero. If a power failure occurs operator or patient can simply push a button on a seat buckle assembly, which will immediately eliminate all distraction forces to the patient.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 2004

Mr. Marc M. Mouser
Senior Project Engineer/Program Reviewer
Conformity Assessment Services
Underwriters Laboratories, Inc.
2600 NW Lake Road,
Camas, Wyoming 98607

Re: K043239
Trade/Device Name: Healthstar Elite
Regulation Number: 21 CFR 890.5900
Regulation Name: Power traction equipment
Regulatory Class: II
Product Code: ITH
Dated: November 17, 2004
Received: November 23, 2004

Dear Mr. Mouser:

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/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

510(k) Number (if known): K043239

Device Name: Healthstar Elite

Indications for Use:

The Healthstar Elite machine administers genuine intervertebral decompression. Each treatment session consists of a physician prescribed treatment period on the Healthstar Elite. A treatment is designed to provide static, intermittent, and cycling distraction forces to relieve pressures on structures that may be causing low back pain. The machine can be used to relieve sciatica pain and pain associated with: bulging or herniated discs, degenerative disc disease, and posterior facet syndrome. It achieves these effects through decompression of intervertebral discs, that is, unloading due to distraction and positioning.

This device is for prescription use only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-CounterUse_____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K043239