

NOV 10 1999

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510(k) Summary**Akron ATP9 Traction Machine**

Submitters Name: Audrey Witko
V.P., Administration & Compliance
Huntleigh Healthcare Inc.
227 Route 33 East
Manalapan, NJ 07726

Telephone: (732) 446-2500

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Name of Device: Akron ATP9 Traction Machine

Manufactured By: Huntleigh Akron
1 Farthing Road
Ipswich, Suffolk IP1 5AP
United Kingdom

Classification Name: Power traction equipment (21 CFR §890.5900) ITH

Predicate Devices: TEC Traction Machine (K834405)
ESCOTEK EST TRAC 401 (K844385)

Device Description:

The ATP9 traction is intended to provide traction and mobilization of lumbar and cervical muscles and vertebrae when used in conjunction with fixed or variable height traction tables. It is indicated for use as a treatment for spinal root impingement, joint hypomobility, degenerative joint disease, discogenic pain, joint pain and compression fractures.

The ATP9 machine mounts on available Akron traction tables and mobile traction stand. Traction force is applied to the patient using Akron traction harnesses. The ATP9 utilizes a DC-powered motor gearbox connected to a rope drum via a clutch. The rope is connected to a harness attached to the patient. The high force hold time and low force rest time programs are selectable from 1 second minimum to 99 seconds maximum, with a high traction force range of 2-200 lbs. and low traction force range of 2-196 lbs. There are seven combinations of therapy including static, intermittent, progressive, regressive and cyclic.

Safety Considerations:

There are eleven fault conditions detected by the ATP9 including, control system Failure, low supply voltage, AC power failure, motor power supply failure, battery failure, excess tension detected, high force control setting failure, strain gauge failure, strain gauge mismatch, motor malfunction, unexpected increase in tension, and cord drive fault. The ATP9 conforms to the following international standards: IEC601-1, EN60601-1-2: 1993, EN60601-1/A2: 1995, EN60601-1-4: 1997. Manufactured to ISO9002 and EN46002.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Audrey Witco
Vice President
Administration, Compliance and Clinical Affairs
Huntleigh Healthcare Incorporated
227 Route 33 East
Manalapan, New Jersey 07726

Re: K992733
Akron ATP9 Traction Machine
Product Code: ITH
Regulatory Class: II
Dated: August 9, 1999
Received: August 13, 1999

Dear Ms. Witco:

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 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 (Pre-market 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 requirement, 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

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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" (21 CFR 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 at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use



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510(k) Number (if known): K992733

Device Name: AKRON ATP9 TRACTION MACHINE

Indications for Use:

The ATP9 traction is intended to provide traction and mobilization of lumbar and cervical muscles and vertebrae when used in conjunction with fixed or variable height traction tables. It is indicated for use as a treatment for spinal root impingement, joint hypomobility, degenerative joint disease, discogenic pain, joint pain and compression fractures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992733

(Optional Format 3-10-98)

(Posted July 1, 1998)

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