K073542 (pg 1/4)

510(k) Summary

Application Sponsor: PT Products, LLC
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Contact Person: Anthony D'Amico, President

FEB 14

Date Prepared: December 11, 2007

Product Description:

Trade Name:	CycleTrac® CT-5000 Automated Cervical Traction Unit
Common Name:	Traction Equipment
Classification Name:	Power Traction Equipment, Class II (21 CFR Section 890.5900)
Product Code:	ITH

Predicate Devices:

Triton/Tru-Trac/TX/Triton DTS Traction
Chattanooga Group, A Division of Encore Medical, L.P.
Regulatory Class: II
Product Code: ITH
510K Number: K053223
Approved February 24, 2006

3D ActiveTrac Hi-Lo Traction Table (Headrest)
The Saunders Group, Inc.
Regulatory Class: II
Product Code: ITH
510K Number: K001712
Approved August 31, 2000

DRS System
Professional Distribution Systems, Inc.
Regulatory Class: II
Product Code: ITH
510K Number: K981822
Approved June 24, 1998

Device Description:

The CycleTrac® CT-5000 Automated Cervical Traction Unit is a device intended to apply intermittent or static traction force to the patients' spine. Unlike other traction devices, the CycleTrac® CT-5000 attaches to a Standard 6 Foot Plinth or a 6 Foot Stationary Chiropractic Adjusting Table (not included). When the CycleTrac® CT-5000 is properly attached to the treatment table it is 26.6 inches long and stands 42 inches off the floor. The CycleTrac® CT-5000 system has a total weight of 14.5 pounds. The traction force is generated by a non-powered, factory certified gas spring capable of generating up to 35 pounds of load. By adjusting the pivot point of the energized spring along the weight index bar, the traction pull force on the traction pull cord can range from 15 to 35 pounds. The engineering principle behind this change in force is the mechanical advantage created when the energized spring pivot point is adjusted along the

510(k) Summary, cont.

weight index bar. As the pivot point moves further from the traction pull cord intercept, the force required to compress the energized spring decreases. As the energized spring pivot point gets closer to the traction pull cord intercept, the mechanical advantage lessens and the force required to compress the energized spring increases. When the pivot point is next to the traction pull cord intercept, there is no mechanical advantage and the force required to compress the energized spring is equal to the maximum output of the energized spring, 35 pounds. The force required to compress the energized spring is equal to the push back force of the energized spring on the traction cord, or the traction pull force on the traction pull cord.

The motorized actuator pulls on the extension linkage attached to the weight index bar, which compresses the energized spring, parking it in the traction OFF position. To return to the traction ON position, the actuator is extended through the extension linkages attached to the weight index bar allowing the energized spring to freely extend, creating a force on the weight index bar. The force on the weight index bar is transferred to the traction pull cord placing the CT-5000 into the traction on position.

The ON-OFF intermittent cervical traction cycle is controlled by the timer. The traction treatment time, traction ON time, and the traction OFF time are pre-set on the timer. The settings are used by the timer to prompt the actuator to extend and retract, which results in the traction ON / traction OFF intermittent cervical traction cycle. Therefore, the timer and the motorized actuator do not contribute to the traction pull force on the patient. The traction pull force is generated solely by the NON POWERED, factory certified, 35 pound energized spring; the CT-5000 does not require power to generate the traction pull force.

The unique headrest design allows for 100% of the traction force toward the occiput without forehead and chin restrains and eliminates the possibility of Temporomandibular Joint problems. The headrest is made of powder coated aluminum and covered with a comfort pad to keep the patient comfortable.

PT Products, Inc. believes that a comparison of the CycleTrac® CT-5000 Automated Cervical Traction Unit to the predicate devices indicates that there are no significant differences between the devices when comparing the cervical traction mode. Therefore, the CycleTrac® CT-5000 Automated Cervical Traction Unit should not raise any concerns about safety and effectiveness.

Intended Use:

The intended use for the CycleTrac® Automated Cervical Traction Unit is to provide a primary treatment modality for the management of neck and back pain. Intermittent/static cervical traction results in cervical disk decompression (unloading due to distraction and positioning) which provides relief of pain associated with a variety of conditions involving anatomical dysfunctions of the spine, including protruding or herniated intervertebral discs, degenerative discs and acute facet problems.

CycleTrac® CT-5000 and Predicate Device Similarities:

- Both systems create a traction pull force.
- Both traction systems use a cord to transmit the traction pull force to a cushioned cradle on which the back of the patient's head rests.
- Both traction systems use the generated traction pull force to create an axial pull in the occiput region of the patient's head.

510(k) Summary, cont.

- With both systems, the pull force (measured in pounds) is adjusted by the system operator.
- Both traction systems deliver cervical traction with the patient in the supine position.
- Both traction systems perform intermittent cervical traction or static cervical traction.
- With both traction systems, the operator can adjust the angle (flexion angle) of traction.
- With both traction systems, the traction treatment time, the traction ON time, and the traction OFF time are adjustable and set by the operator.
- Both traction systems have an emergency call cord.
- Both traction systems use a cushioned cradle, which can be adjusted to conform to the width of the patient's neck.
- Both traction systems automatically go into the traction OFF position at the end of the patient's traction session.
- To alert the operator that the patient's traction session is over, both traction systems beep repeatedly at the conclusion of the traction session.
- Both traction systems automatically power OFF at the conclusion of a traction session.

CycleTrac® CT-5000 and Predicate Device Differences:

- The CT-5000 traction unit requires low voltage DC input to the system (12 volts DC, 3 amperes). The CT-5000 has a UL medically approved power supply that takes common 120 or 220/240 volt AC power and converts it to the required 12 volts DC, 3 amperes system input. The predicate device (Chattanooga Traction Table TXE-1 and TXF-1, with the Saunders Cervical Headrest) requires a high voltage AC input to the system (120 volt AC or 220/240 volt AC).
- The CT-5000 cervical traction pull force range is 16-36 pounds. The predicate device pull force range is 0-50 pounds.
- The CT-5000 does not require the use of head straps to remain in the proper position during traction. The head strap constraint used by the predicate device can produce pressure marks on the patient's forehead and can cause discomfort. In addition, the lack of a head strap on the CT-5000 allows the patient to terminate treatment by simply lifting their head from the headrest assembly, or by using the call cord button to stop the traction therapy.
- The cervical pull force applied by the energized gas spring on the CT-5000 is fixed and will never be greater than the initial calibrated value of 35 pounds. Because the traction force delivered to the patient is independent of the electric motor, in the event of a motor malfunction, the traction force can never exceed the force of the gas spring. The predicate device is capable of pulling up to 200 pounds, which exceeds the predicate device use range of 0-50 pounds of pull force.

510(k) Summary, cont.

- The CT-5000 emergency call cord is removable, making it replaceable in the case of malfunction. The predicate device emergency call cord is fixed, making it more difficult to replace.

- The CT-5000 headrest pad has a calibration scale for the V-Block spacing that can be recorded for each patient to allow for comfort from treatment to treatment. The predicate device does not have a calibration setting.

Signed,

_____ _____

Anthony D'Amico
President
PT Products, LLC

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2008

PT Products
% Mr. Anthony D'Amico
President
362 Eckford
Troy, MI 48098

Re: K073542
Trade/Device Name: CycleTrac® CT-5000 Automated Cervical Traction Unit
Regulation Number: 21 CFR 890.5900
Regulation Name: Power traction equipment
Regulatory Class: Class II
Product Code: ITH
Dated: December 13, 2007
Received: December 18, 2007

Dear Mr. D'Amico:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K073542 (pg 1/1)

Indications for Use Statement

510(k) Number: Pending – Original Application

Device Name: CycleTrac® CT-5000 Automated Cervical Traction Unit

Indications for Use: The CycleTrac® Automated Cervical Traction Unit provides a primary treatment modality for the management of neck and back pain. Intermittent/static cervical traction results in cervical disk decompression (unloading due to distraction and positioning) which provides relief of pain associated with a variety of conditions involving anatomical dysfunctions of the spine, including protruding or herniated intervertebral discs, degenerative discs and acute facet problems.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brudnick

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073542