

**510(k) Summary - K053223**

**FEB 24 2006**

**SUBMITTER:** Chattanooga Group,  
A Division of Encore Medical, L.P.  
4717 Adams Road  
Hixson, TN 37343

**CONTACT PERSON:** Michael Treas  
Manager of Regulatory Affairs  
Phone: (423) 870-2281 ext. 7207  
Fax: (423) 870-7404

**DATE PREPARED:** February 22, 2006

**DEVICE TRADE NAME:** Triton/ Tru-Trac/ TX/ Triton DTS Traction

**COMMON/ USUAL NAME:** Powered Traction Equipment

**CLASSIFICATION** Class II (Product Code ITH)

**PREDICATE DEVICES** K051938 - Triton/ Tru-Trac/ TX Traction,  
K844385 - Eskotek EST Trac 401 Traction,  
K992733 - Akron ATP9,  
K053503 - VAX-D Genesis System,  
K031862 - SpineRx-LDM,  
K001361 - Jilco,  
K030060 - SpineMed,  
K972487 - EMG Retrainer,  
K881416 - MyoTrac

**DEVICE DESCRIPTION:**

The Chattanooga Group powered traction device consists of an electric traction treatment unit, and may be sold with the following: EMG (a.k.a. sEMG) biofeedback feature, Pull-Pattern intermittent traction preset feature, patient traction treatment table device, positioning bolster accessories, patient traction belt accessories, high volt pulsed electrotherapy device and miscellaneous traction devices and/ or accessories. The device is intended to be used in hospitals, physical therapy clinics and chiropractic clinics for treatment in static, intermittent, progressive, regressive and cyclic, distraction forces to relieve pressures on structures that may be causing pain of skeletal or muscular origin (cervical, thoracic, lumbar, hip, wrist, shoulder). The device is restricted to sale by or on the order of a licensed physician or licensed practitioner.

The primary features of the Triton/ Tru-Trac/ TX/ Triton DTS Traction hardware are the traction unit (a.k.a. traction head), display screen, traction rope, mounting assembly and patient stop treatment switch.

The EMG biofeedback feature is used to detect muscle activation and relaxation for cervical and lumbar traction therapy. The treating clinician determines the minimum muscle activation or minimum muscle relaxation threshold set point. This is done by utilizing the visual display. The intermittent traction reacts to these threshold settings and administers prescribed traction treatment. The Pull Pattern feature is a preset of intermittent traction settings, less the setting of traction force, less setting of traction time. Force and time parameters are determined by the treating clinician.

**STATEMENT OF TECHHICAL CHARACTERISTICS COMPARISON**

A comparison of device features demonstrate that the Triton/ Tru-Trac/ TX/ Triton DTS Traction device is substantially equivalent to the following devices:

Predicate device name and product code	510(k) number
Triton/ Tru-Trac/ TX Traction ITH, Powered Traction Equipment	K051938
Eskotek EST Trac 401 Traction (a.k.a. Tru-Trac 401) ITH, Powered Traction Equipment	K844385
Akron ATP9 Traction Device ITH Powered Traction Equipment	K992733
VAX-D Genesis System Traction Device ITH, Powered Traction Equipment	K053503
SpineRx-LDM Traction Device ITH, Powered Traction Equipment	K031862
Jilco Traction Device ITH, Powered Traction Equipment	K001361
SpineMed Traction Device ITH, Powered Traction Equipment	K030060
EMG Retrainer HCC, Biofeedback	K972487
MyoTrac HCC, Biofeedback	K881416

**Declarations of Conformity**

The Triton/ Tru-Trac/ TX/ Triton DTS Traction devices is in compliance with the following FDA recognized Consensus Standards:

UL 60601-1: 2003, Standards for Medical Equipment Part 1: General Requirements for Safety, 1<sup>st</sup> Edition

IEC 60601-1-2: 2001, Medical Electrical Equipment Part 1 – 2: General requirements for Safety - Collateral Standard, Electromagnetic Compatibility – Requirements and Tests, 2<sup>nd</sup> Edition

**Truthful and Accurate Statement**

A statement attesting to the truthfulness and accuracy of the information contained in this submission is attached in Section 3.

**Further Information**

In the event that additional information is required, please contact:

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Manager of Regulatory Affairs  
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Hixson, TN 37377 U.S.A.  
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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 24 2006

Chattanooga Group  
c/o Mr. Michael Treas  
Manager of Regulatory Affairs  
4717 Adams Road  
Hixson, Tennessee 37343

Re: K053223

Trade/Device Name: Triton/Tru-Trac/TX/Triton DTS Traction  
Regulation Number: 21 CFR 890.5900  
Regulation Name: Powered traction equipment  
Regulatory Class: II  
Product Code: ITH  
Dated: February 7, 2006  
Received: February 9, 2006

Dear Mr. Treas:

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.

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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) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

A handwritten signature in black ink, appearing to read "M. Melkerson". The signature is written in a cursive style with a large initial "M".

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

Enclosure

510(k) Number (if known): K 053223  
 Device Name: Triton/ Tru-Trac/ TX/ Triton DTS Traction

Indications for Use:

The Triton/ Tru-Trac/ TX/ Triton DTS Traction devices provide traction and mobilization of skeletal structures and skeletal muscles.

The Triton/ Tru-Trac/ TX/ Triton DTS Traction devices provide a treatment in static, intermittent, progressive, regressive and cycling distraction forces to relieve pressures on structures that may be causing pain of skeletal or muscular origin (cervical, thoracic, lumbar, hip, wrist, shoulder). Therapeutic distraction can be applied in a variety of programmable patterns, cycles and functions.

The Triton/ Tru-Trac/ TX/ Triton DTS Traction devices with the optional EMG (a.k.a. sEMG) biofeedback feature may be used to relieve peripheral radiation/sciatica and pain associated with:

➤ Protruding discs	➤ Spinal root impingement
➤ Bulging discs	➤ Hypomobility
➤ Herniated discs	➤ Degenerative joint disease
➤ Degenerative disc disease	➤ Facet syndrome
➤ Posterior facet syndrome	➤ Compressions fractures
➤ Acute facet problems	➤ Joint pain
➤ Radicular pain	➤ Discogenic pain
➤ Prolapsed discs	

EMG (a.k.a. sEMG)

Determination of the activation magnitude and timing of muscles for: a) retraining of muscle activation b) coordination of muscle activation
Determination of the force produced by muscle for control and maintenance of muscle contractions
Relaxation muscle training
Muscle re-education

Prescription Use  (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use  (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)

*[Signature]*  
 (Division Sign-Off)

**Division of General, Restorative,  
 and Neurological Devices**