

K093553

AUG 13 2010

**510(k) SUMMARY**

**Perseus Athletics LLC  
POSTURETEK Spinal Curvature Monitor**

**Name of Device**

Trade or Proprietary Name: POSTURETEK  
Common Name: posture trainer  
Classification Name: spinal curvature monitor  
Product Code: LZW

**Preparation Date**

August 12, 2010

**510(k) Sponsor**

Perseus Athletics, LLC  
8 Turtleback Road  
Essex, MA 01929

**510(k) Sponsor Contact**

Keith A. Barritt  
Fish & Richardson P.C.  
1425 K Street, N.W., Suite 1100  
Washington, DC 20005  
Phone: (202) 783-5070  
Facsimile: (202) 783-2331

**Intended Use**

The PostureTek Shirt provides training to help the wearer use his own muscles to maintain the desired posture, thereby correcting poor posture and improving appearance.

### **Technological Characteristics and Substantial Equivalence**

The POSTURETEK spinal curvature monitor is designed to be worn as a shirt, bra, tank top, or the like. Threaded in the garment is a monofilament, the tension of which changes depending upon the wearer's posture. If the wearer's posture is poor, an electronic disc located in the armpit region of the garment gently vibrates, alerting the wearer to correct his or her posture. The POSTURETEK device is easy to use, discrete, and durable.

The POSTURETEK spinal curvature monitor is substantially equivalent to the ZEGRA Posture Trainer (K#081540) and the Spine Tuner (K#951244) for purposes of FDA market authorization. All of these devices alert the wearer when improper posture occurs. Although the precise mechanics of their systems may vary, the devices are substantially equivalent in that they have the same intended use of improving posture and have similar general technological characteristics.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Perseus Athletics LLC  
% Fish & Richardson P.C.  
Mr. Keith A. Barritt  
1425 K Street, N.W.  
11<sup>th</sup> Floor  
Washington, District of Columbia 20005

AUG 13 2010

Re: K093553  
Trade/Device Name: PostureTek  
Regulatory Class: Unclassified  
Product Code: LZW  
Dated: August 10, 2010  
Received: August 11, 2010

Dear Mr. Barritt:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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

Enclosure

K093553

AUG 13 2010

### Indications for Use

510(k) Number (if known): 093553

Device Name: PostureTek

Indications For Use:

The PostureTek Shirt provides training to help the wearer use his own muscles to maintain the desired posture, thereby correcting poor posture and improving appearance

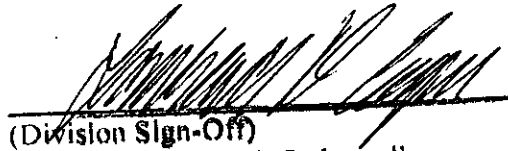
Prescription Use   X    
(Part 21 CFR 801 Subpart D)

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)



(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

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