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 Althetics, 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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.
11Th 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.

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 1 3 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 AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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

510(k) Number K093553