Revised 510(k) Summary

FEB 20 2009

Type:	Traditional
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Preparation date:	January 23rd, 2009
Trade name:	ZEGRA Posture Trainer
Common name:	Posture trainer
Classification name:	Monitor, Spine Curvature
Class:	unclassified
Product code:	LZW
Panel:	Physical Medicine
Substantial equivalence:	Device Classification Name - Monitor, Spine Curvature 510(k) Number - K951244 Device Name - SPINE TUNER POSTURE TRAINER Applicant - Dan Kline, 1816 West Cliff Ct, Carlsbad, CA 92008 Contact - Dan Kline Classification Product Code - LZW Date Received - 03/13/1995 Decision Date - 06/26/1995 Decision - Substantially Equivalent (SE) Classification Advisory Committee - Physical Medicine Review Advisory Committee - Physical Medicine Statements/Summary/Purged Status - Statement Only Type - Traditional Reviewed By Third Party - No

The submitter was informed by FDA staff, that the predicate device "SPINE TUNER posture trainer" is an unclassified pre-amendments device. Thus he expects that the Classification Advisory Committee "Physical Medicine" will classify the substantially equal "ZEGRA posture trainer" in the same way.

Device description:	The ZEGRA Posture Trainer is worn and looks just like the predicate posture trainer by the name of SPINE TUNER (510k Number: K951244). It is strapped around the chest with a belt or a bra. All electronic components sit in a little plastic case. The case contains a part that is moved when the user slumps. This movement is picked up by a sensor within the case. When the ZEGRA Posture Trainer is switched on, a microprocessor records the current posture as posture threshold. Thereafter, the ZEGRA Posture Trainer will vibrate whenever this threshold posture is reached or surpassed by slumping too much. The user has a choice of immediate feedback or feedback with a few seconds delay. The ZEGRA Posture Trainer has no cables and no options for connecting with other devices. It is exclusively battery powered.
Intended use:	The intended use of the ZEGRA Posture Trainer is a postural reminder for people who have the habit of slumped posture, who wish to be reminded of their posture whenever they slump beyond a predetermined limit, and who have the ability to correct their posture. The ZEGRA Posture Trainer's feedback helps to reduce slumped posture within this population.
Substantial equivalence:	A sensor and feedback unit encased in a plastic housing. The housing being attached to the body via a belt or bra. The sensor being sensitive to spinal curvature. A vibratory feedback signal whenever and as long as the spine is flexed beyond a predetermined limit. Battery power as the only energy source. A target population that wants to improve its posture and has the ability to do so.
Main difference to predicate:	The ZEGRA posture trainer has a choice of immediate and delayed feedback, while the predicate device only offers immediate feedback.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Peter Fischer
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Mr. Peter Fischer
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Germany

FEB 20 2009

Re: K081540
Trade Name: ZEGRA Posture Trainer
Regulatory Class: Unclassified
Product Code: LZW
Dated: January 23, 2009
Received: February 3, 2009

Dear Mr. Fisher:

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 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

Indications for Use

510(k) Number (if known): K081540

Device Name: ZEGRA Posture Trainer

Indications For Use:

The intended use of the ZEGRA Posture Trainer is a postural reminder for people who have the habit of slumped posture, who wish to be reminded of their posture whenever they slump beyond a predetermined limit, and who have the ability to correct their posture. The ZEGRA Posture Trainer's feedback helps to reduce slumped posture within this population.

The intended use is for Prescription Use and Over-The-Counter Use.

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)

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

510(k) Number K081540