SEP 20 2012

510(k) Summary

K Number

K121590

General Information

Classification	Unclassified
Trade Name	Sway Balance™
Submitter	Capacity Sports, LLC 624 S. Boston Ave., Suite 700 Tulsa, OK 74119 Tel: (918) 728-1688 Fax: (918) 712 1833
Contact	Pamela M. Buckman, MSN Buckman Company, Inc. 2800 Pleasant Hill Rd., Suite 175 Pleasant Hill, CA 94523 Tel: 925 980 7007 Fax: 925 705 7381

Indications for Use

The Sway™ Balance System is intended for use to assess sway as an indicator of balance. Individual suitability for assessment must be judged on a case by case basis, by a qualified individual including those certified and/or licensed in their state to prescribe and/or use balance devices such as certified athletic trainers and coaches, physical therapists, nurses and physicians. Conditions affecting postural sway include nausea, headache, orthopedic injury, ear infection, medications, head injury, dehydration and fatigue. The Sway™ Balance System can be used wherever an iOS mobile operating device is available.

Predicate Device(s)

Korebalance™ by SPORTKAT, LLC (K070676)

Device Description

The Sway Balance™ System is a mobile measurement system that analyzes balance through thoracic sway, using the built in accelerometer of a mobile device. The Sway Balance™ System is a stand-alone mobile operating system software application that does not include any peripheral hardware add-ons.

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Materials

The Sway Balance™ System is a software only solution that utilizes the hardware of the Apple iOS mobile operating system for products such as the iPhone 3G, 3GS, 4, 4S, iPad, iPad2 and iPod Touch. The built in accelerometer is accessed to analyze motion during a balance test.

Testing

Device testing was conducted to evaluate conformance to product specification. The results showed the system met specification. Product verification consisted of studies comparing the Sway Balance™ System to force platform technology. Bench testing analyzed the sensitivity of the software program to access data from the ST Microelectronics MEMS Accelerometer built into the smartphone compatible with the Sway Balance™ Software. Sensitivity scores using the Sway Balance™ Software were comparable.

Clinical testing included studies comparing the Sway Balance™ System to force platform assessment tools to establish positive correlations between the two devices. Results showed no significant difference between the two data sets ($p = <0.05$). Mean Actual Stability Scores on the balance platform was 1.41 ± 0.90 compared to 1.38 ± 0.72 using the mobile device.

Studies also analyzed performance of balance tasks of varying difficulty to measure the device's effectiveness in determining levels of stability. Data showed that the Sway Balance™ System results were consistent with expected outcomes. Within subject reliability was evaluated under conditions of instantaneous acceleration forces.

Summary of Substantial Equivalence

The Sway Balance™ System is equivalent to the predicate product. The intended use, targeted population and basic premise underlying the balance assessment are equivalent.

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

SEP 20 2012

Capacity Sports, LLC
c/o Pamela M. Buckman, MSN
Buckman Company, Inc.
2800 Pleasant Hill Rd., Suite 175
Pleasant Hill, CA 94523

Re: K121590
Trade/Device Name: Sway Balance™
Regulation Name: Vestibular Analysis Apparatus
Regulatory Class: Unclassified
Product Code: LXV
Dated: August 8, 2012
Received: August 10, 2012

Dear Ms. Buckman:

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,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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Intended/Indications for Use

510(k) Number:	K121590
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X
Prescription Use (Per 21 CFR 801 Subpart D)

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

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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X
Prescription Use
(Per 21 CFR 801.109)