April 2, 2018

King-Devick Technologies, Inc.
Lori Grover
Senior Vice President, Health Policy
Two Mid America Plaza, Suite 110
Oakbrook Terrace, IL 60181

Re: K173669
Trade/Device Name: K-D Balance
Regulatory Class: Unclassified
Product Code: LXV
Dated: February 27, 2018
Received: March 1, 2018

Dear Lori Grover:

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.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Eric A. Mann -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173669

Device Name
K-D Balance

Indications for Use *(Describe)*
K-D Balance is an objective balance assessment tool and is intended to be used for individuals for whom a balance measurement is a desired outcome. K-D Balance is intended for use to assess balance performance. Individual suitability for assessment must be judged on a case by case basis, by a qualified individual including those certified or licensed in their state to prescribe and use balance devices including but not limited to athletic trainers and coaches, physical therapists, nurses, physicians, and other health care providers. Patients with conditions that could affect balance include, but are not limited to, vestibular dysfunction, nausea, headaches, orthopedic injury, inner ear infection or dysfunction, neurological conditions, head injury, medication side effects, dehydration and fatigue. K-D Balance can be used wherever an iOS mobile operating device is available. K-D Balance may only be used by health care professionals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Trade Name	**K-D Balance**
Common Name	Balance Test Application
Classification	Unclassified
Product Code	LXV
Submitter	Lori Grover, OD, PhD King-Devick Technologies, Inc Two Mid America Plaza, Suite 110 Oakbrook Terrace, IL 60181 Tel: (630) 501-0281 Fax: 630-501-0285
Preparation Date	October 17, 2017 ***(revised March 30, 2018)***
Predicate Device	Sway Balance ™ by Capacity Sports, LLC (K121590)

Device Description

K-D Balance is a mobile balance test to be used on the 6th generation iPhone or iPod touch with iOS versions 9.0 or later. K-D Balance measures balance using motion sensors already built-in to the iPhone or iPod touch devices. K-D Balance utilizes a proprietary algorithm that calculates a balance score based on the analysis of subject movements detected by the device's internal accelerometer. Balance is measured during a series of stances with the mobile device secured to the subject with a device holder. Health care professionals follow the step-by-step voice guidance that runs after launching the app during the entirety of the test to ensure consistency in obtaining balance measures. K-D Balance does not function as a diagnostic test, and K-D Balance results should be interpreted by healthcare professionals only.

Indication For Use

K-D Balance is an objective balance assessment tool and is intended to be used for individuals for whom a balance measurement is a desired outcome. K-D Balance is intended for use to assess balance performance. Individual suitability for assessment must be judged on a case by case basis, by a qualified individual including those certified or licensed in their state to prescribe and use balance devices such as certified athletic trainers and coaches, physical therapists, nurses, physicians, and other health care providers. Patients with conditions that could affect balance include, but are not limited to, vestibular dysfunction, nausea, headaches, orthopedic injury, inner ear infection or dysfunction, neurological conditions, head injury, medication side effects, dehydration and fatigue. K-D Balance can be used wherever an iOS mobile operating device is available. K-D Balance may only be used by health care professionals.

Technological Characteristics

K-D Balance and Sway Balance both run on iOS mobile devices. K-D Balance is compatible with 6th generation iPhone and iPod Touch. K-D Balance software will continually update to run on future generations of these iOS mobile devices. Sway Balance functions on iPhone 4, iPhone 5, 4th and 5thgenerations of iPod Touch, and iPads, according to the Sway Balance website (https://swaymedical.com/resources/faqs; last visited March 20, 2018).

Both applications use built-in iOS mobile device accelerometers to calculate the output balance score. The output score reflects how much movement occurred during each assessment. Balance scores are measured on a 0 to 100 scale, and scores closer to 100 are considered closer to normal, with 100 being a perfect score. The point spread may vary between K-D Balance and Sway based on differences in algorithms, however the output scores are comparable and repeatable.

Performance Testing

Device testing was conducted to evaluate conformance to product specification. K-D Balance met specification. Performance testing verified that K-D Balance and Sway Balance System are in statistical agreement. Bench testing analyzed the sensitivity of the software to access data from the ST Microelectronics MEMS Accelerometer built into the mobile device that is compatible with the K-D Balance application. Sensitivity scores with K-D Balance were comparable.

Performance testing was completed by the University of Texas, Southwestern Medical Center, Neurology and Sports Medicine Department. K-D Balance and Sway Balance testing were performed simultaneously (two trials) for a total of 79 male and female subjects (25 males, 54 females; mean age: 38.63 ± 12.88, range: 18-65) with and without brain injury or other neurological conditions (34 injured vs 45 non-injured). Balance measures were obtained for a total of three stances, which included the double leg stance, right tandem stance, and left tandem stance. The amount of movement, or sway, was calculated by each balance test application algorithm using data generated by the mobile device accelerometer. A device holder secured the iPhone 6 with K-D Balance and the subject held the other mobile device with Sway Balance.

K-D Balance measures were in statistical agreement with Sway Balance outcomes for both normal and balance deficit groups for the double leg, tandem right, and tandem left leg stances according to the linear regression analysis and Deming Regression Model. The statistical agreement between the two tests support substantial equivalence of K-D Balance to Sway Balance for double leg, tandem right, and tandem left leg stances. Poorer balance scores were observed for subjects with balance deficits, which included subjects with brain injury. No adverse effects or complications were encountered during or after performance testing.

Summary of Substantial Equivalence

K-D Balance proved to be substantially equivalent to the predicate application, Sway Balance System. Both applications assess sway during specific stances to generate an objective measure of balance. K-D Balance and Sway Balance utilize the same internal accelerometers built-into iOS mobile devices, and each contain proprietary algorithms within their software that calculates the output balance score. K-D Balance is a safe, effective tool in assessing balance performance in subjects who have balance difficulties or may be at-risk for balance issues.

	Sway Balance ™	K-D Balance
Intended Use	The Sway™ Balance System is intended to assess sway as an indicator of balance, particularly when screening for deviations in postural sway as a possible symptom. The system is not intended to diagnose or treat any medical condition or disease. It is designed to provide an affordable, convenient and portable screening tool for balance assessment and should not replace an evaluation by a medical professional. (obtained from Sway's website: https://swaymedical.com/resources/faqs)	K-D Balance's intended use is to provide an objective balance assessment utilized by health professionals in monitoring subject balance performance. K-D Balance is not intended to diagnose, screen, or treat a medical condition. K-D Balance functions as an iOS application that can be administered quickly and easily.
Indication for Use	Individual suitability for use of the Sway™ Balance System 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. "Sway provides a portable outreach solution for community concussion management and fall risk screening to increase referrals." The Sway Balance System can be used wherever an iPhone 4, iPhone 5, 4th and 5thgenerations of iPod Touch, and iPads are available.	K-D Balance is an objective balance assessment for individuals who are under the supervision of a health professional. K-D Balance testing should be performed on a case by case basis by a health professional with valid certification or licensure in the state to prescribe or use balance devices. K-D Balance assessments can be useful in monitoring balance performance particularly for conditions that impair balance including: vestibular dysfunction, nausea, headaches, orthopedic injury, inner ear infection or dysfunction, neurological conditions, head injury, medication side effects, dehydration and fatigue. K-D Balance can be used wherever a 6th generation iPhone and iPod Touch or later is available with or without an internet connection.
Target Population	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. Sway Balance System is for concussion management and fall risk screening as well.	Individuals suitable for assessment must be judged on a case by case basis by a certified and/or licensed health care provider. Health professionals may use K-D Balance to assess balance performance, but not to be interpreted as a diagnostic test.
Where Used	The Sway Balance System can be used wherever an iPhone 4, iPhone 5, 4th and	K-D Balance can be used wherever a 6th generation iPhone and iPod Touch or

	5th generations of iPod Touch, and iPads are available.	later is available with or without an internet connection.
Design	iOS mobile software application	iOS mobile software application
Materials	iOS mobile devices (iPhone 4, 5, iPod Touch and iPad 5) 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, iPad, and iPod Touch. The built-in accelerometer is accessed to analyze motion during a balance test.	iOS mobile devices (6th generation or later iPhone and iPod Touch) The built-in iOS mobile device accelerometer is accessed to analyze motion during the balance assessment. K-D Balance utilizes tri-axial coordinate data from the internal accelerometers of mobile devices to determine a single quantitative, objective balance score through measurements of pitch, yaw, roll and jerk.