October 22, 2019

Quadrant Biosciences
Bryan Greene
Vice President - Operations
505 Irving Avenue
Syracuse, New York 13210

Re: K183661
Trade/Device Name: ClearEdge Balance System
Regulation Number: 21 CFR
Regulation Name: N/A
Regulatory Class: Class II
Product Code: LXV
Dated: September 20, 2019
Received: September 23, 2019

Dear Bryan Greene:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Vasant Dasika
Acting Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K183661

Device Name
ClearEdge® Balance System

Indications for Use *(Describe)*
The ClearEdge® 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, physical therapists, chiropractors, nurses and physicians. The ClearEdge® Balance System can be used wherever compatible Android mobile operating devices can be used.

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.

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510(k) Summary

1. **Date Summary Prepared:** 21 October 2019

2. **Submitter:** Quadrant Biosciences
dba Motion Intelligence, Inc.
505 Irving Avenue, Suite 3100AB
Syracuse, NY 13210
Contact: Bryan Greene
Ph: 315-614-2325 ext 1001

3. **Trade Name:** ClearEdge Balance System

4. **Common Name:** Recorder, Attention Task Performance

5. **Device Description:** The ClearEdge® Balance System is a mobile software system that analyzes balance through measurements of postural sway. The System is comprised of application software, and accompanying hardware consisting of a mobile computing device, proprietary sensor, balance pad, and friction pad. The test data is collected, uploaded to a HIPAA compliant server, analyzed by Motion Intelligence developed algorithms and presented in report form for clinician's review. The reports indicate how a subject's balance score may have changed between testing sessions, and whether the measured change is likely due to measurement error and normal human variation in performance of the selected balance stance or a real change in performance caused by an external factor.

   Using proprietary software on an Android tablet and the Edge Sensor, the ClearEdge Balance System tests balance by administering eight select balance stances.

6. **Indication for Use:**

The ClearEdge® 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, physical therapists, chiropractors, nurses and physicians. The ClearEdge® Balance System can be used wherever compatible Android mobile operating devices can be used.

7. **Classification:**

Regulation:	Unclassified
Class II	510(k)
Product Code:	LXV
Classification	Unclassified
Panel:	Ear Nose & Throat

8. **Predicate Device(s):**

510(k) Number:	K121590
Manufacturer:	Capacity Sports, LLC
Trade Name:	Sway™ Balance System
Product Code:	LXV
Classification:	Unclassified

9. **Compliance to Special Controls / Performance Standards: Compliance to the following recognized consensus standards is declared:**

Technical / Product-Related Standards:

- IEC 60601-1:2012 Ed 3.1 General requirements for basic safety and essential performance, FDA#19-5
- IEC 60601-1-2:2014 Ed 4 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests, FDA #19-8
- IEC 60601-1-6 Issued: 2013/10/29 Ed: 3.1 Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability, FDA #5-89
- IEC 60601-1-11 Issued: 2015/01/20 Ed. 2 Medical Elec. Equip.- Part 1-11: Gen. Req. for Basic Safety & Essential Performance - Collateral Standard - Req. for Medical Elec. Equip. & Medical Elec. Systems Used in the Home Healthcare Environment, FDA #19-14
- IEC 60529:2013 Degrees Of Protection Provided By Enclosures (IP Code), FDA #None
- 47CFR Part 15 Federal Communications Commission (FCC), FDA #None
- ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirement, FDA #5-90

Quality System, Risk Management & Process-Related Standards:

- 21CFR820: Part 820 – Quality System Regulations, FDA #None
- IEC 62366 Issued: 2014/01/28 Ed. 1.1 Medical Devices - Application of Usability Engineering to Medical Devices, FDA #5-87
- IEC 62304:2006 Medical device software - Software life cycle processes, FDA #13-8
- ISO 14971:2012 Medical devices - Application of risk management to medical devices, FDA #5-40
- HIPAA Compliant, FDA #None

10. **Technological Characteristics**

The main differences between Motion Intelligence, Inc.'s ClearEdge Balance System, Model 1055, and the Predicate Devices the Sway Balance System cleared under K121590 are the following:

- The ClearEdge Balance® System measures postural sway with a proprietary sensor located at a person's center of mass, midline at approximately L5, while the Sway Balance system measure postural thoracic sway, using the built-in motion sensors of any iOS device.
- The Sway Balance System is a mobile application that must be downloaded and run on an iOS mobile device that is supplied by the end user. The ClearEdge Balance System provides The Edge Sensor, friction pad, and balance pad to the end user and requires a mobile application that must be downloaded and run on an COTS Android device.
- ClearEdge Balance System provides the Edge Sensor to measure the patient's balance. Sway Balance System relies on the accelerometer provided in iOS mobile operating devices.
- ClearEdge Balance System and Sway Balance System use different methods in comparing the results on a series of balance stances. According to the predicate's public clearance records, Sway provides a comparison of raw scores on each balance stance and a comparison of test score against patients' average score. ClearEdge Balance provides a comparison of raw scores on each balance stance, and a comparison of raw scores on each balance stance overlaid with threshold lines representing the Minimal Detectible Change (MDC) for that test.

Other minor differences between ClearEdge Balance System and the Sway Balance System predicate also include:

- The ClearEdge Balance System provides the user with some of the hardware that is needed to use the system
- ClearEdge Balance System uses the Android operating system; Sway Balance System uses Apple's iOS
- ClearEdge Balance System uses a tablet; Sway Balance System uses smartphones or tablets.
- The ClearEdge Sensor is powered by 3 AAA batteries, and the Sway Balance System uses the iPhone's lithium ion battery

11. **Comparison Table**

Feature	ClearEdge Balance System Model 1055 (System Under Review)	Sway™ Balance System (Cleared under K121590)	Comments
FDA Regulation, Number, Product Code & Description	Unclassified, LXV, Apparatus, Vestibular Analysis	Unclassified, LXV, Apparatus, Vestibular Analysis	Same.
Intended Use	The ClearEdge® Balance System is a mobile software system that analyzes balance through postural sway. The System is comprised of application software and accessory hardware, consisting of a mobile computing device, proprietary sensor, balance pad, and friction pad. The System measures the amount of motion of a subject's center of gravity, while the subject attempts to maintain various body posture stances, and translates the amount of motion into a numeric score.	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.	Both devices are mobile measurement systems that analyzes balance through either postural (proposed) or thoracic (predicate) sway. Both devices measure the amount of motion of a subject while maintaining a body posture stance and translate the amount of motion into a score that represents balance. The difference in measuring the type of sway is a function of where the sensor/accelerometer is physically located. The subject device places the sensor on the subject's lower back, while the predicate device is held against the chest. The subject device uses a proprietary sensor with a built-in accelerometer while the predicate device uses the iPhone's accelerometer. Neither of these issues raise new questions of safety of effectiveness.
Indication for Use	The ClearEdge® 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, physical therapists, chiropractors, nurses and physicians. The ClearEdge® Balance System can be used wherever compatible Android mobile operating devices can be used.	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.	Both devices measure acceleration and motion and convert the measurements into a numeric balance score between 0 and 100, and both devices have the same intended users and use environments.
Intended User	Certified athletic trainers, physical therapists, nurses, chiropractors, and physicians who are licensed to prescribe and/or use balance devices.	Certified athletic trainers and coaches, physical therapists, nurses and physicians who are licensed to prescribe and/or use balance devices.	Same intended users.
Intended Use Environment	Anywhere mobile devices can be utilized	Wherever an iOS mobile operating device is available	Both devices use mobile platforms.
Target Patient Population	Athletes. Patients with balance issues	Athletes. Patients with balance issues	Same targeted patient populations.
Contraindications	Contraindications: Improper Testing Unstable Surfaces Wet or Slippery Surfaces Cluttered Environments Distractive Environments	Contraindications: Improper Testing Unstable Surfaces Wet or Slippery Surfaces Cluttered Environments Distractive Environments	Same contraindications.

Feature	ClearEdge Balance System Model 1055 (System Under Review)	Sway™ Balance System (Cleared under K121590)	Comments
	Improper environment may lead to inaccurate results or cause harm to the patient A patient with an injury should not be tested, but instead given medical attention	Improper environment may lead to inaccurate results or cause harm to the patient A patient with an injury should not be tested, but instead given medical attention	
Use limitations	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	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	Identical use limitations.
System-Level Components	The ClearEdge® Balance System is a mobile measurement system that analyzes balance through postural sway. As shipped, the ClearEdge Balance System includes: the Edge Sensor- a proprietary sensor, a Friction Pad, a Balance Pad, and a Carrying Case. The user must download the software onto an approved tablet	The Sway Balance System is a software solution that utilizes the hardware of the Apple iOS mobile operating system for products such as the iPhone 3G, 3G5, 4, 4S, iPad, iPad2 and iPod Touch. The built in accelerometer of these devices is accessed to analyze motion during a balance test.	Fundamentally, both systems are software programs that require the user to provide the operating platform. Both have the same/equivalent components and offering some of the needed hardware components as part of the system does not raise and new questions of safety or effectiveness.
Additional Required Components	The ClearEdge® Balance System requires the user to provide a tested and approved Android tablet, a stylet (for data input) and headphones (for use with the tablet)	Sway Balance System requires the user to provide an Apple iOS mobile device	The ClearEdge Balance System requires the user to download the software onto an Android tablet, a mobile device, while the Sway balance system requires the user to download the software onto an iPhone, also a mobile device.
Testing Methods	The ClearEdge Balance System tests for balance by utilizing the Edge Sensor to measure acceleration and motion. The Edge Sensor is attached to a subject with a belt, located over the lower back, which is near the anatomical center of mass.	Using the built-in motion sensors of any iPhone, iPad or iPod Touch* device and Sway's mobile application, health professionals can administer a medical grade objective balance test in virtually any setting.	Both devices measure balance using an accelerometer which is then displayed on a mobile device. The differences in accelerometers (proprietary versus iPhone) and platform (Android versus iOS) does not raise new questions of safety or effectiveness.
Testing Protocol	The ClearEdge Balance System tests eight difference balance stances, while measuring postural sway with a proprietary sensor located at a person's center of mass, midline at approximately L5. The stances include a combination of feet together stance, tandem stance, eyes open, eyes closed, on a firm surface, and on the balance pad provided in the system.	To administer a test, an athlete or patient is instructed to press the mobile device against their chest with both hands, while performing a five-test protocol that includes a combination of bipedal (feet together) stance, tandem stance and single leg stance positions. Sway measures thoracic postural sway using the built-in motion sensors of any iOS device to estimate balance.	Both testing protocols are based on balance stances. Although there are slight variations in implementation, the basis of the stances for each device is fundamentally similar. Both devices measure sway via accelerometers. The Edge Sensor is placed at a person's center of mass to measure postural sway and Sway Balance places an iOS device at a person's chest to measure thoracic postural sway. The differences do not raise any new questions of safety or effectiveness.
Scoring/Results	The ClearEdge Balance System recommends each individual complete a baseline test for post event comparison since individual balance will vary person to person. For each of the balance stances, the Edge Sensor measures the patient's postural sway using an accelerometer at 250 packets/second. For each test, the patient's relative motion is converted to a balance score	The Sway score is intended to provide an individualized baseline of each athlete or patient's own ability to maintain postural control during the testing conditions. Balance scores vary for each individual and should be compared to each individual's "normal" baseline. Sway Balance reports balance scores on 0 to 100 scale for each individual tests. A composite score is reported,	Both devices recommend each individual complete a baseline test since postural balance will vary for each individual. Both systems report the balance result on a 0-100 scale, reporting the scores for each individual tests, as well as a composite average score. Both devices use known statistical methods to evaluate the balance scores that they compute in a similar manner. These methods of statistical analysis are well known and

Feature	ClearEdge Balance System Model 1055 (System Under Review)	Sway™ Balance System (Cleared under K121590)	Comments
	on a 0 to 100 scale with a higher number representing less motion and a lower number representing more motion. . ClearEdge Balance is used to track changes in balance scores over time. Comparisons between the Reference Test and each Comparison Test are based on a determination of whether the difference between the Reference Test scores and Comparison Test scores (Difference Scores) are large enough to represent difference in performance. A Minimum Detectable Change (MDC) is used to determine the threshold size of a Difference Score that must be present to be deemed significant at a prescribed statistical confidence level.	which is calculated by averaging the patient's individual scores for each of the five balance tests.	the differences in analytic comparison of balance scores do not raise any questions of safety or effectiveness. Reference Device KOREBALANCE ™, K070676, for monitoring over time, "Quantitative measurement of patient balance performance while the patient executes a preprogramed set of maneuvers or protocols…The patient results are scored and saved (the information is not a clinical measurement but provides a reproducible quantitative measurement that the therapist can use to plan and monitor therapy)…in conjunction with the therapist's observations, to assess patient progress over the course of multiple…sessions."
Power Source	Edge Sensor requires 3 AAA batteries The mobile device operates on lithium ion rechargeable battery	Mobile device operates on lithium ion rechargeable battery	Both devices operate on battery power. The type of battery (AAA versus lithium ion) does not raise any new questions of safety or effectiveness.
Device Type	Sensor with accelerometer	iOS mobile device with accelerometer	Nearly identical outputs and performance, other than marketing approaches that do not raise any questions of safety or effectiveness.
Measurement	Kinetic energy/balance	Kinetic energy/balance	
Delivery System	Results shown on mobile device or other web capable device	Results shown on mobile device or other web capable device	
Patient Contact/Interface Materials	Mobile device, Edge Sensor	Mobile device	Nearly identical patient contact/interface methods. Including a separate motion sensor is done for improved user experience. Doing so raises no new questions of safety (no new biocompatibility issues) or effectiveness.
Hardware Specifications	Tablet	Hardware of the Apple iOS mobile operating system for products such as the iPhone 3G, 3G5, 4, 4S, iPad, iPad2 and iPod Touch.	Nearly identical hardware specifications.
Mobile Operating System	Android	iOS	Mobile operating systems are similar and the differences between Android and iOS in this application do not raise any questions of safety or effectiveness.
User Input Mechanism	Stylus	Unknown	Similar User Input Mechanisms.
Display	Tablet	iPhone 3G, 3G5, 4, 4S, iPad, iPad2 and iPod Touch.	Nearly identical display.
Dimensions	Case dimensions: 4 3/4" h x 16 1/2"w x 20 7/8"l	Software only (the hardware is provided by the iPhone, but was excluded from consideration in their 510(k) application)	ClearEdge has provided some hardware components needed for ease of the customers and marketing purposes. There are no questions of safety to the patient.
Weight	Under 15 lbs.	N/A (the hardware is provided by the iPhone, but was excluded from consideration in their 510(k) application)	ClearEdge has provided some hardware components needed for ease of the customers and marketing purposes. There are no questions of safety to the patient.

Feature	ClearEdge Balance System Model 1055 (System Under Review)	Sway™ Balance System (Cleared under K121590)	Comments
Operating Environment	Normal environment where the temperature and humidity are maintained for normal human comfort.	Information not available, but assumed to be normal environment where the temperature and humidity are maintained for normal human comfort.	Within reasonable assumptions, the operating environments are the same.
Storage Environment	Store in a dry location between 0°C / 32°F and 45°C / 113°F. Do not store items in direct sunlight. All items should be stored in their designated space in the ClearEdge Balance System storage case	Software only, no storage required (the hardware is provided by the iPhone, but was excluded from consideration in their 510(k) application)	ClearEdge has provided some hardware components needed for ease of the customers and marketing purposes. There are no questions of safety to the patient.
Standards	Technical / Product-Related Standards: • IEC 60601-1:2012 Ed 3.1 General requirements for basic safety and essential performance • IEC 60601-1-2:2014 Ed 4 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests • IEC 60601-1-6 Issued: 2013/10/29 Ed: 3.1 Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability • IEC 60601-1-11 Issued: 2015/01/20 Ed. 2 Medical Elec. Equip.- Part 1-11: Gen. Req. for Basic Safety & Essential Performance - Collateral Standard - Req. for Medical Elec. Equip. & Medical Elec. Systems Used in the Home Healthcare Environment • IEC 60529:2013 Degrees Of Protection Provided By Enclosures (IP Code), FDA #None • 47CFR Part 15 Federal Communications Commission (FCC) • ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirement Quality System, Risk Management & Process-Related Standards: • 21CFR820: Part 820 – Quality System Regulations	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, 3G5, 4, 4S, iPad, iPad2 and iPod Touch. The built in accelerometer is accessed to analyze motion during a balance test. Note: With the above in mind, it is assumed that Sway Balance did NOT consider the iPhone be a medical device (even though the their SW platform is completely dependent on the iPhone's accelerometer) and did not conduct any electrical safety / EMI testing.	The proposed device was designed and testing according to the applicable standards, importantly including testing to IEC 60601-1-2, 4th edition for EMC compatibility in a "home use" environment. The predicate devices did not. However, ensuring compliance does not raise questions of safety.

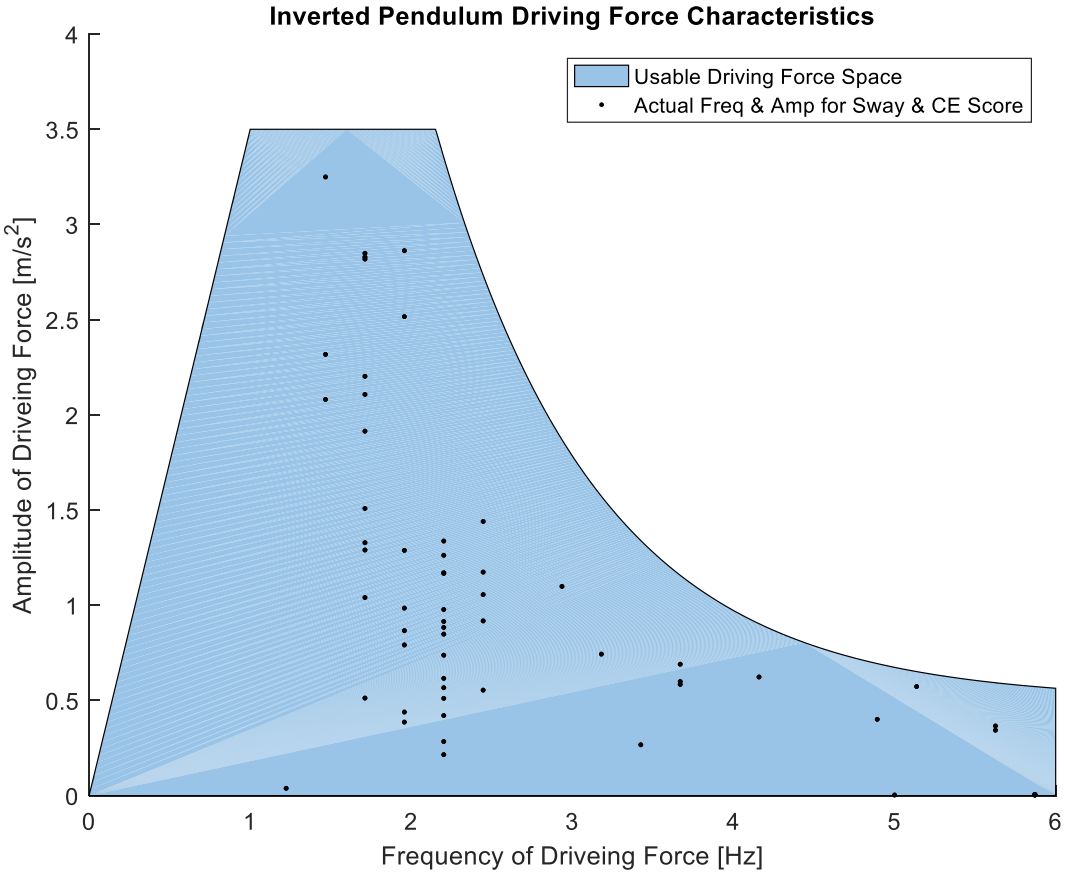
Feature	ClearEdge Balance System Model 1055 (System Under Review)	Sway™ Balance System (Cleared under K121590)	Comments
	• IEC 62366 Issued: 2014/01/28 Ed. 1.1 Medical Devices - Application of Usability Engineering to Medical Devices • IEC 62304:2006 Medical device software - Software life cycle processes • ISO 14971:2012 Medical devices - Application of risk management to medical devices HIPAA Compliant		

12. **Performance Testing; Laboratory and Human Performance**:

Equivalence between ClearEdge Balance and Sway Balance assessment of balance was demonstrated by Laboratory Testing and supplemental human performance testing. Laboratory Testing compared ClearEdge Balance and Sway Balance scoring of movements of an inverted pendulum. Correlation of ClearEdge Balance and Sway Balance scores were evaluated using linear regression and Deming regression. Linear regression: r values for all tests were greater than .97, and the slopes of the linear regression lines for the tests ranged between .92 and 1.05 ($p<.001$). Deming regression: 95% confidence interval for slope contains the value 1, 95% confidence interval for intercept contains the value 0. Supplemental clinical testing compared ClearEdge Balance and Sway Balance scores for 34 subjects on Sway Balance tests (Power > 80%) using a Two One Sided Test Procedure (TOST). The upper end of the 90% confidence interval for the difference between means of ClearEdge Balance and Sway Balance scores (Confidence Interval) was less than the upper end of the equivalence margin ($p<.001$), and the lower end of the Confidence Interval was greater than the lower end of the equivalence margin ($p<.001$). Substantial equivalence was demonstrated because the Confidence Interval is contained within the equivalence margin.

Laboratory Testing Summary:

The driving force of the inverted pendulum can be adjusted in frequency and amplitude. The following figure shows the available input frequencies and amplitudes. The blue area represents the available combinations of frequency and amplitude, and the dots represent the actual frequency and amplitude that produced one of the sets of data.



These data only represent the input driving force, the sensors themselves measure the spectrum of motion as an output and convert that to a score.

A simple model of human standing is given by an inverted pendulum, a one-dimensional, classical model for the motion of a single, massive particle. A standing human is approximated as a single mass (located at the center of mass) separated from the ground by a massless rod of fixed length L. The feet are treated as attached to the ground by a fulcrum, such that the center of mass can only undergo motion along an arc of radius L around the feet---thus the mechanics of the system are described by the tilt angle θ, representing the angular displacement of the center of mass from directly above the feet, with the rod positioned normal to the ground.

In quiet standing, a subject uses ankle muscles and hip muscles to change the center of pressure necessary to keep changes in the center of mass over the area of the ground in contact with the feet. The center of pressure is located at various positions in the area under and between the soles of the feet in contact with the ground. The ankle muscles are used to generate changes in the center of pressure to control changes in the center of mass in the anterior – posterior direction and

the hip muscles are used to generate changes in the center of pressure to control changes in the center of mass in the medial – lateral direction. The difference in the center of pressure and the center of gravity at any time is proportional to the motion and acceleration of the center of mass in the horizonal plane (anterior-posterior and medial-lateral directions). The difference between center of mass and center of pressure is the control system used by the human balance control system. See Winter, D. A. (1995). Human balance and posture control during standing and walking. *Gait & Posture*, 3(4), 193-214. The motion and acceleration in the horizonal plane is mathematically related to the angular acceleration around the axis between the center of mass and the ground. The pendulum model therefore is an accurate representation of the muscle induced motions of the body to maintain the standing posture. The pendulum is perfectly balanced when the mass is positioned directly above the pivot point; however, a very slight displacement of the mass from this position will cause the pendulum to tip over.

Humans can overcome this difficulty and maintain standing balance, at which the system is at equilibrium, by maintaining active control of the position of their center of mass relative to the fulcrum formed by their feet. For small displacements, the ankles work to exert a torque that counteracts gravity and prevents the individual from falling over. The timescale that this restoring force must act to recover equilibrium is proportional to the period of a simple pendulum, demonstrated as $T = 2\pi\sqrt{\frac{L}{g}}$

Precise measurements of active balancing can be made by filming an individual standing, and digitally tracking the location of the center of mass after the individual is tilted forward by a known angular displacement at t=0.

Supplemental human performance testing summary:

Supplemental human performance testing was performed to confirm the substantially equivalent balance scores generated by Sway and CE Balance in the laboratory testing performed on the inverted pendulum apparatus in the laboratory performance testing. This supplemental human performance testing consisted of using Sway and CE Balance simultaneously to generate balance scores on 34 subjects who were tested on the five Sway balance stances. 29 subjects were healthy and 5 had some neurologic condition.

The balance scores generated by Sway and ClearEdge Balance on all five Sway stances were combined for comparison. The results of all stances were combined because the Sway predicate reports an aggregate score for all stances combined and the laboratory testing comparing Sway and ClearEdge demonstrated that their respective balance scores were highly correlated across all ranges of motion. The comparison of Sway and ClearEdge on the human performance testing was done using a Two One Sided Test (TOST).

The TOST compares the difference between the mean Sway scores on all stances and the mean ClearEdge scores on all stances in relation to an equivalence margin. The equivalence margin was set at +10 to -10, because that margin ensured that the effect size due to the equivalence margin would be significantly less (.4) than the standard deviation of the difference scores.

The TOST compares the difference between Sway and ClearEdge means to the upper and lower equivalence margins using a t statistic. The TOST t statistic is computed for each margin by subtracting ±10 from the difference between means of the Sway and ClearEdge balance scores and dividing the result by the pooled standard deviation of the difference scores. The p values of the two t statistics are then determined from the appropriate t distribution.

- The significance level for the p values necessary to show substantial equivalence for the TOST was set at .05, which demonstrates that the confidence interval around the difference in Sway and ClearEdge means at the 90% level of confidence lies inside of the equivalence margin. The p values for the human performance TOST were .0008 for the lower equivalence margin and .00007 for the upper equivalence margin, which satisfied the condition to demonstrate substantial equivalence.

13. **Summary of MDC Development**

The Minimal Detectible Change (MDC) for each of the eight stances used in ClearEdge Balance testing was developed with a test-retest repeatability study, in which 144 subjects were tested on two occasions separated by varying relatively short periods of time (most time intervals between the two tests were less than 50 days). 109 subjects were healthy and 35 had some neurologic condition. Subjects were included in the study only if they had no injury or change in symptoms between the two tests.

The difference between each subject's score on each stance on the two test occasions were calculated and the difference scores were found to be normally distributed for each stance used in the ClearEdge Balance testing, which is a condition to use of the MDC to define the boundaries of expected variation in results on a repeated test.

The MDC is the size of a change in balance score that represents statistical real change in performance and not measurement error and normal human variation. The measurement error for ClearEdge Balance was determined using the Standard Error of Measurement (SEM) statistic. The MDC was calculated for the 95% confidence level; which is the size of a change in balance score that has only a 5% probability of being caused by measurement error. The MDC is proportional to the SEM ($1.96 \times \sqrt{2} \times SEM$ for the 95% confidence level). Numeric values for the SEM and MDC differ for each balance stance, but the MDC for each test represents the threshold for separating real change in performance of the balance stance from measurement error at the 95% confidence level.

14. **Comparison Summary / Conclusion**

The proposed ClearEdge Balance System (Model 1055) and its predicate device, the Sway Balance System cleared under K121590 share the same intended use, intended users, intended use environment and indications for use. Furthermore, the proposed devices and the predicate systems have the same/equivalent technological characteristics, physical characteristics and safety standards, user interfaces, contraindications and applicable standards. The differences that exist between the devices, relating to their mobile operating system, physical size, and weight and appearance do not affect the relative safety and/or effectiveness. Thus, the proposed ClearEdge Balance System (Model 1055) and its predicate device, the Sway Balance System cleared under K121590, are substantially equivalent.