



August 16, 2019

Highmark Innovations Inc. DBA Highmark Interactive  
% E.J. Smith  
Consultant  
Smith Associates  
1468 Harwell Avenue  
Crofton, Maryland 21114

Re: K190735  
Trade/Device Name: EQ Balance  
Regulation Name: Vestibular Analysis Apparatus  
Regulatory Class: Unclassified  
Product Code: LXV  
Dated: July 12, 2019  
Received: July 18, 2019

Dear E.J. Smith:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Srinivas Nandkumar, Ph.D.  
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

## Indications for Use

510(k) Number (if known)  
K190735

Device Name  
EQ Balance

### Indications for Use (Describe)

EQ Balance is intended to assess body tilt 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. Interpretation of EQ Balance results should only be made by a healthcare professional, as part of a multifaceted assessment of balance. Conditions affecting postural sway include nausea, headache, orthopedic injury, ear infection, medications, head injury, dehydration and fatigue. EQ Balance should be used in an indoor setting free from obstructions and free from excessive noise or visual distractions. EQ Balance should be only be used as directed by your healthcare practitioner. EQ Balance may be used on mobile devices running iOS or Android operating systems.

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.

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## 510(k) Summary

**Trade Name**

Common Name

Classification

Product Code

Predicate Device

**EQ Balance**

Balance Test Application

Unclassified

LXV

Sway Balance™ by Capacity Sports, LLC (K121590)

Company Name:

Company Address:

Telephone:

email:

Contact Person:

Highmark Interactive

1 University Avenue, 3<sup>rd</sup> Floor

Toronto, Ontario, Canada M5J 2P1

416.320.0286

[david@highmark.tech](mailto:david@highmark.tech)

David Crane, Senior Product Manager

Summary Preparation Date:

August 14, 2019

**PREDICATE DEVICE:**

| Manufacturer         | Brand Name    | 510(k) Number |
|----------------------|---------------|---------------|
| Capacity Sports, LLC | Sway Balance™ | K121590       |

**DEVICE DESCRIPTION:**

EQ Balance is a mobile balance test to be used on mobile phone and tablet devices with iOS version 10.3 or later, or Android OS version 6 or later. EQ Balance measures balance using the accelerometer within the device.

EQ Balance utilizes an 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 held to the chest by the user. Users 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. EQ Balance does not function as a diagnostic test, and EQ Balance results should be interpreted by qualified individuals only.

**INDICATIONS FOR USE:**

EQ Balance is intended to assess body tilt 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. Interpretation of EQ Balance results should only be made by a healthcare professional, as part of a multifaceted assessment of balance. Conditions affecting postural sway include nausea, headache, orthopedic injury, ear infection, medications, head injury, dehydration and fatigue. EQ Balance should be used in an indoor setting free from obstructions and free from excessive noise or visual distractions. EQ Balance should be only be used as directed by your healthcare practitioner. EQ Balance may be used on mobile devices running iOS or Android operating systems.

**PREDICATE PRODUCT COMPARISON TABLE:**

| Features                      | Highmark Interactive                                                                                                                                                                                                                                                                                                                                                                                                                                                | Capacity Sports, LLC                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Comments                 |
|-------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Identify Predicate Device     | EQ Balance                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Sway Balance™                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                          |
| 510(k) Number:                | K190735                                                                                                                                                                                                                                                                                                                                                                                                                                                             | K121590                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                          |
| Indications for use statement | EQ Balance is intended to assess body tilt 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. Interpretation of EQ Balance results should only be made by a healthcare professional, | 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, | Substantially Equivalent |

| Features                     | Highmark Interactive                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Capacity Sports, LLC                                                                                                                                                                                                                                                                                  | Comments                 |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
|                              | as part of a multifaceted assessment of balance. Conditions affecting postural sway include nausea, headache, orthopedic injury, ear infection, medications, head injury, dehydration and fatigue. EQ Balance should be used in an indoor setting free from obstructions and free from excessive noise or visual distractions. EQ Balance should be only be used as directed by your healthcare practitioner. EQ Balance may be used on mobile devices running iOS or Android operating systems. | medications, head injury, dehydration and fatigue. The Sway™ Balance System can be used wherever an iOS mobile operating device is available.                                                                                                                                                         |                          |
| Use Environment / Where used | Mobile tablet/phone running iOS and Android operating systems.<br><br>The testing is intended to be done on a firm and flat surface in an area free from visual or auditory distraction.                                                                                                                                                                                                                                                                                                         | Mobile tablet/phone running iOS and Android operating systems.<br><br>A controlled environment on a flat, hard surface.<br><br>(Sway's website: <a href="https://swaymedical.com/resources/faqs">https://swaymedical.com/resources/faqs</a> )                                                         | Substantially Equivalent |
| 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 such as certified athletic trainers and coaches, physical therapists, nurses and physicians.                                                                                                                                                                                            | 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. | Substantially Equivalent |

| Features                                                                     | Highmark Interactive                                                                                                                                                                                                     | Capacity Sports, LLC                                                                                                                                                                                                                                                                                                                    | Comments                 |
|------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Stand Alone Software                                                         | Yes                                                                                                                                                                                                                      | Yes                                                                                                                                                                                                                                                                                                                                     | Same                     |
| Electronically record objective performance measurement (speed and accuracy) | Yes                                                                                                                                                                                                                      | Yes                                                                                                                                                                                                                                                                                                                                     | Same                     |
| Design                                                                       | Android and iOS-based mobile software application                                                                                                                                                                        | Android and iOS-based mobile software application                                                                                                                                                                                                                                                                                       | Substantially equivalent |
| Materials                                                                    | EQ Balance is a software-only solution that uses the hardware via the Apple iOS and Android OS mobile operating systems for products.<br>The built-in accelerometer is accessed to analyze motion during a balance test. | The Sway Balance™ System is a software only solution that uses the hardware of the Apple iOS mobile operating system* for products such as the iPhone 3G, 3GS, 4, 4S, iPad, iPad2 and iPod Touch.<br>The built-in accelerometer is accessed to analyze motion during a balance test.<br><br><i>*Now also compatible with Android OS</i> | Substantially equivalent |

## DISCUSSION OF TECHNOLOGICAL DIFFERENCES:

EQ Balance and Sway Balance both run on iOS and Android mobile devices. EQ Balance is compatible with iPhone, iPad and iPod touch devices running iOS version 10 and up as well as devices using Android OS version 6 and up. EQ Balance will continually update to run on future generations of these mobile devices. Sway Balance functions on iPhone, iPad and iPod touch devices running version iOS 9.3 or later, or Android OS version 6 and up, according to the app store marketplaces where this app is distributed.

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. Scores closer to 100 are considered closer to normal with 100 being a perfect score. The point spread may vary between EQ Balance and Sway based on differences in algorithms, however the output scores are comparable and repeatable.

## **NONCLINICAL TESTING:**

Device testing was conducted to evaluate conformance to product specification. EQ Balance met specification. Nonclinical (“bench”) testing analyzed the accuracy of the tilt angles coming from the accelerometer in the mobile devices that are compatible with the EQ Balance application. Accuracy with EQ Balance were comparable. Testing was conducted using a sample of Apple device models running the iOS operating system and sample of Samsung device models running the Android operating system.

Test documentation has been provided according to the FDA Guidance for the Content of Premarket Submissions for Software, including software Verification and Validation reports and Bench Testing. The design and testing was conducted according to IEC 62304 Medical Device Software –Software Life Cycle Processes and ISO 14971 Medical Device –Application of Risk Management to Medical Devices.

## **CLINICAL STUDY:**

Performance testing verified that EQ Balance and the Sway™ Balance System (Sway) are in statistical agreement.

Clinical testing was completed under an IRB-approved study at a sports medicine and concussion clinic in Mississauga, Ontario under the oversight of a principle investigator from the Department of Neurosurgery at the University of Toronto. EQ Balance and Sway Balance testing were performed simultaneously (two trials) for a total of 70 male and female subjects (25 males, 45 females; mean age:  $37.8 \pm 14.8$ , range: 13-65) with and without balance impairment, determined by failure of the modified Balance Error Scoring System (mBESS) test (26 balance-impaired). Participants performed three postures, that were analyzed, while holding the mobile device against their chest. Balance measures were then obtained simultaneously with Sway Balance and EQ Balance during each of the stances, which included the double leg stance, right tandem stance, and left tandem stance. Participants held a device holder that secured two devices: one iPhone 6s (Apple, Cupertino, CA, USA) with EQ Balance and a second iPhone 6s with Sway Balance. The amount of movement was calculated by each balance test application algorithm using data generated by the mobile device accelerometer. The primary output (“3-pose average”) was calculated as the average of the balance performance on the 3 stances.

The following table summarizes EQ Balance scores by pose and by group: Healthy vs. Impaired balance

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| <b>Healthy balance (N=44)</b> |                      |                    |                     |                       |
|-------------------------------|----------------------|--------------------|---------------------|-----------------------|
| <b>Pose:</b>                  | <b>Feet together</b> | <b>Tandem left</b> | <b>Tandem right</b> | <b>3-pose average</b> |
| <b>Minimum</b>                | 87.7                 | 40.7               | 62.5                | 70.5                  |
| <b>5th percentile</b>         | 87.8                 | 74.4               | 68.0                | 83.0                  |
| <b>Median</b>                 | 94.0                 | 90.0               | 91.4                | 91.0                  |
| <b>95th percentile</b>        | 96.2                 | 95.2               | 94.8                | 94.3                  |
| <b>Max</b>                    | 96.7                 | 96.4               | 95.0                | 95.4                  |

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| <b>Impaired balance (N=26)</b> |                      |                    |                     |                       |
|--------------------------------|----------------------|--------------------|---------------------|-----------------------|
| <b>Pose:</b>                   | <b>Feet together</b> | <b>Tandem left</b> | <b>Tandem right</b> | <b>3-pose average</b> |
| <b>Minimum</b>                 | 78.8                 | 42.6               | 28.0                | 49.8                  |
| <b>5th percentile</b>          | 79.2                 | 42.7               | 31.2                | 51.2                  |
| <b>Median</b>                  | 89.4                 | 75.5               | 73.3                | 78.9                  |
| <b>95th percentile</b>         | 97.5                 | 94.0               | 92.8                | 93.0                  |
| <b>Max</b>                     | 98.0                 | 95.0               | 93.2                | 93.1                  |

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*5% percentile means 5% of the data is below this value; 95% percentile means 95% of the data below this value*

According to the Spearman's analysis, the 3-pose average measures calculated by EQ Balance were in statistical agreement with the 3-pose average obtained with Sway Balance for both normal and balance-impaired groups, and for all three stances (double leg, tandem right and left). The Deming Regression Model showed agreement between the 3-pose average balance measures (the primary device output), as well as 23 of the 27 additional analyses that were conducted. The statistical agreement between the two tests supports substantial equivalence of EQ Balance to Sway Balance. Poorer balance scores were observed for subjects with balance impairments. No adverse effects or complications were encountered during or after performance testing.

Consistency of the EQ Balance measure was conducted by calculating the intra-class correlation (ICC) on two consecutive EQ Balance tests. The ICC for the cohort was ICC=0.75 ( $p<0.001$ ). This analysis demonstrates strong consistency of the task output between test sessions.

#### **SUMMARY OF SUBSTANTIAL EQUIVALENCE:**

EQ Balance is based on the legally market predicate device Sway Balance (K121590), with the same intended use. There are some differences in technological characteristics which do

not raise different questions of safety and effectiveness, such as different proprietary algorithms used in the software for calculation of output balance score. Through clinical testing and other information (e.g. software, cybersecurity) according the agency's guidance document, we have demonstrated that the subject device EQ Balance is substantially equivalent to the predicate device Sway Balance.