February 15, 2025

Sway Medical, Inc.
% Robert Steurer
Consultant
Steurer Consulting Group, LLC
800 Blue Quail Rd
Keller, Texas 76248

Re: K241737
Trade/Device Name: Sway System Sports Plus
Regulation Number: 21 CFR 882.1471
Regulation Name: Computerized Cognitive Assessment Aid For Concussion
Regulatory Class: Class II
Product Code: POM
Dated: January 15, 2025
Received: January 15, 2025

Dear Robert Steurer:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Jay R. Gupta -S

Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Sway System Sports Plus

Indications for Use *(Describe)*
The Sway System Sports Plus is intended for use as a computerized cognitive assessment test to aid in the assessment and management of concussion in individuals ages 18-24.

The Sway System Sports Plus is indicated for use when there is a suspected concussion or head injury.

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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Date Prepared:	February 12, 2025
Submitter:	Sway Medical, Inc. 32 S. Lewis Ave. Tulsa, OK 74101
Submitter Contact:	Sway Medical, Inc. 32 S. Lewis Ave. Tulsa, OK 74101 Name: Alex Pettigrew Sway Medical Inc Phone: (281) 726-3820 Email: alex.pettigrew@swaymedical.com
Application Correspondent:	Robert Steurer Principal Consultant Steurer Consulting Group 800 Blue Quail Rd. Keller, TX 76248 steurerbob@gmail.com +1 (425) 358-1072
Manufacturing Site:	Sway Medical, Inc. 32 S. Lewis Ave. Tulsa, OK 74101
Trade Name:	Sway Sports+
Common Name:	Neurological Diagnostic Device
Classification Name:	Computerized Cognitive Assessment Aid for Concussion
Device Class:	Class II
Primary Classification Regulation:	21 CFR §882.1471

Primary Product Code: POM

Predicate Device: Impact Applications, Inc. ImPACT Quick Test, K170551

Reference Predicate Device: Impact Version 4, K202485

Substantially Equivalent Devices:

New Device	*Predicate Device*	*Reference Predicate Device*
Sway Sports Plus (Sports+) Sway Medical, Inc.	ImPACT Quick Test K170551 Impact Applications, Inc.	ImPACT Version 4 K202485 ImPACT Applications, Inc.

Device Description:

Sway Sports Plus (referred to as Sway Sports+) is a licensed variant of the Sway System and is a software solution (SaMD) that provides a computerized cognitive assessment aid for concussion. This prescription device uses an individual's score(s) on a battery of cognitive tasks to provide an indication of the current level of cognitive function in response to a suspected concussion. The computerized cognitive assessment aid for concussion is used only as an assessment aid in the management of concussion to determine cognitive function for patients after a potential concussive event where other diagnostic tools are available and does not identify the presence or absence of concussion. The examiner may have the patient complete the Sway Balance test to provide an additional indicator in their assessment of concussion. The Sway System is not intended as a stand-alone diagnostic device. After the patient completes the Sway Sports+ test(s), the examiner can view the summary statistics for each test such as mean reaction time (speed).

Sway Sports+ does not create new information through analysis or interpretation, nor does it offer any diagnostic or treatment recommendations. The Sway Sports+ is not intended to be used as a standalone diagnostic device.

Sway Sports+ operates in the Apple iOS or Android operating systems, enabling it to be used on the hardware of Apple iPhone, iPad, and iPod Touch, or Android mobile devices. The internal accelerometer is accessed to analyze motion of the device in response to stimuli during testing. The mobile device hardware is not provided by Sway Medical.

Environments where Sway Sports+ may be used may include both clinical and non-clinical settings. Clinical settings may include physician offices, hospitals, physical or occupational therapy clinics, skilled nursing facilities, assisted living centers and other healthcare facilities where cognitive tests may be evaluated. In addition, non-clinical environments may include sports team's locations where the application may be used on the sideline to perform a cognitive assessment, e.g., fitness centers, gymnasiums, or stadiums. It is recommended that the tests be taken in a supervised environment for baseline and post-injury testing.

Sway Sports+ consists of the Sway Balance (K121590) and the Sway Computerized Cognitive Assessment Aid. The Sway Computerized Cognitive Assessment Aid (PTY) is exempt from 510(k).

Intended Use:	The Sway System Sports Plus is intended for use as a computerized cognitive assessment test to aid in the assessment and management of concussion in individuals ages 18-24. The Sway System Sports Plus is indicated for use when there is a suspected concussion or head injury
Summary of Substantial Equivalence:	The Intended Use of Sway Sports+ is the same as the predicate device, ImPACT QT, and the reference predicate device, ImPACT. The patient age range for Sway Sports+ is contained within that of the predicate and reference devices. Sway Sports+ and the predicate device function on mobile devices incorporating Apple iOS; Sway Sports+ also functions on Android OS devices. Sway Sports+, the predicate device, and the reference device all enable the administration of neuropsychological tests to evaluate a test taker's cognitive state. All devices are similar in terms of technological characteristics, as they administer neurocognitive test modules using standard off-the-shelf computing devices and record objective cognitive performance measurements as the test taker responds to stimuli presented on the screen. Sway Sports+ also includes balance assessments; balance has been documented in the scientific literature as a potential indicator of the effects of concussion. Sway Sports+ differs from the predicate and reference devices in the content and design of the cognitive tasks. However, both Sway Sports+ and the predicate device provide the same reporting on the mobile application, on a web portal, and in .pdf format. The reference device also has reporting available on a web portal and in .pdf format. Both summary and raw data are available as an export for all devices. Sway Sports+ uses internal accelerometer and gyroscope data from mobile devices as well as touch input to record patient responses. The predicate device relies solely on touch input, and the reference device uses input from computer peripherals. This is not a significant difference, as all devices include a response signal to the underlying operating system as part of their algorithms.
Technology Comparison:	The Sway Sports+ employs the same technological characteristics as the predicate device and the reference device.

Table 1 – Substantial Equivalence Comparison			
Characteristic	**Sway Sports Plus (Sports+)**	**Predicate Device** ImPACT Quick Test (K170551)	**Reference Device** ImPACT Version 4 (K202485)
Operating System	Apple iOS and Android mobile devices	Apple iOS mobile devices	Desktop/laptop computers
Use Cases	Measures change over time	Same	Same
Patient Population	18-24 years old	12-70 years old	12-80 years old
How Provided	Software only	Same	Same
Reporting Features	Report viewable on the Sway Mobile Application and on the Sway Web Portal and in .pdf format. Summary and Raw Data is available as csv export from the web portal data.	Report viewable in PDF format. Summary and Raw Data available in csv, xml, and html file formats.	Same
Technology	Stand-alone software application	Same	Same
Stimulus Presentation	Mobile device screen	Same	Desktop or laptop screen
Stimulus Capture (test taker response)	User input (motion response) via mobile device motion sensors and via touch screen	User input (finger touch) via mobile device touch screen	User input via computer peripherals.
Cognitive Tasks Administered	Test battery consisting of multiple test modules: -Module 1: Reaction Time -Module 2: Impulse Control -Module 3: Inspection Time -Module 4: Memory Test, including three letter delayed recall and working memory	Test battery consisting of multiple test modules: -Module 1: Symbol Match -Module 2: Three letter memory and reverse number counting -Module 3: Attention Tracker	Test battery consisting of multiple test modules: -Module 1: Word Memory and Delayed Memory Recognition -Module 2: Design Memory and Delayed Design Recognition -Module 3: X's and O's -Module 4: Symbol Matching -Module 5: Color Match Module 6: Three Letter Memory
Additional Tests/Input	Balance Test; Symptom Tracker; Patient Demographics	Symptom Tracker; Patient Demographics	Same as predicate device

Results Interpretation	The Sway System does not provide a recommendation that the patient is impaired vs. unimpaired. Clinical interpretation of the results includes a normative database for Clinical comparison.	Same	Same
Psychometric Properties	Demonstrates construct validity with traditional neuropsychological test and test-retest reliability	Same	Same
Standards Used	ISO 14971 IEC 62304 IEC 62366	ISO 14971 IEC 62304	Same
Key Clinical Outcomes	***Validity***: r values range from 0.22 to 0.42 when compared to traditional neuropsychological testing; similar small to moderate correlations when compared to the predicate device. ***Reliability***: ICC values range from 0.68 to 0.92 for one-week test-retests intervals	***Validity***: r values range from 0.28 to 0.61 when compared to traditional neuropsychological testing. ***Reliability***: r values range from 0.18 to 0.83	***Validity***: r values range from 0.37 to 0.70 when compared to traditional neuropsychological testing. ***Reliability***: ICC values range from 0.50 to 0.88 for test-retest intervals less than 30 days.

Sterilization and Shelf-life	Sway Sports+ is a software product. Sway Sports+ does not have a shelf-life. Therefore, this section is not applicable.
Biocompatibility	Sway Sports+ is a software product and does not directly nor indirectly contact the patient. Therefore, this section is not applicable.
Software Testing	Sway Sports+ was designed and developed according to Sway Medical, Inc.'s, internal software development process in accordance with IEC 62304. Sway Sports+ was tested using verification and validation methods, the results of which indicate the Sway Sports+ complies with its specifications.
Electrical Safety	Sway Sports+ is a software product. Therefore, this section is not applicable.
Electromagnetic Compatibility Testing	Sway Sports+ is a software product. Therefore, this section is not applicable.

Performance Testing – Bench

Sway Sports+ was developed and validated in accordance with IEC 62304, Medical Devices – Software Life Cycle and the FDA Guidance documents "General Principles of Software Validation" and "Applying Human Factors and Usability Engineering to Optimize Medical Device Design" that are appropriate for software development. Software verification and validation activities, including design phase reviews, risk management, traceability and software testing for performance, were all executed to demonstrate compliance with predetermined specifications.

Non-Clinical Testing

A summary of the Non-Clinical Performance Bench Testing is included in Table 2.

Table 2 – Summary of Non-Clinical Performance Testing	
Test Performed	Documents: Software Testing as part of Verification and Validation; Documents: • PRJ-2303-02 Verification and Validation Report • PRJ-2211-04 Usability Validation Protocol • PRJ-2303-03 Usability Validation Results
Device Description	The Sway Sports+ is a software product capable of running on Android v9.0 or later and Apple iOS v13 or later. The software was tested on both platforms.
Test Method/ Applicable Standards	The Sway Sports+ was tested per Verification and Validation protocol and criteria to ensure product meets product requirements. The results of the testing are included in PRJ-22303-02 Verification and Validation Report along with Usability Testing
Acceptance Criteria	The actual (observed) results conform to the specified expected results.
Unexpected Results/ Significant Deviations	None
Results	All tests pass with no exceptions. System meets requirements specifications.

Performance Testing – Clinical

This 510(k) submission includes a literature review of studies that demonstrate the validity, reliability, normative data, and clinical use of Sway Sports+. Data was collected to examine test-retest reliability in healthy controls, test-retest reliability in concussed patients, and the sensitivity & specificity of the product in the concussed population.

While Sway Sports+ is not intended to be used to classify a patient as having a concussion, it may be useful to create criteria based on the device's output to classify a patient as concussion positive or negative, to allow comparison to predicate devices to support a substantial equivalence determination. This information, along with additional data that demonstrate the device's test-retest reliability, construct validity, and reliability of outputs in patients with concussion, was used to support a determination of substantial equivalence.

Summary of Clinical Testing:

Normative Database

De-identified baseline test data was collected from over 126,000 users aged 18 to 24 years old. Subjects were selected based on the following inclusion criteria: Completed a baseline test in English, completed a baseline test in the United States of America, primary language was English, did not report a concussion within the last 6 months, did not report neurological conditions, did not report learning disability, had valid scores on all tests. Data were stratified across age and gender. Mann-Whitney U statistical tests were used to assess inter- and intra-sex and age differences in Sway balance and cognitive test module scores. Descriptive statistics (mean, standard deviation, median, and interquartile range [10th, 25th, 75th, and 90th]) were calculated for all Sway tests. Statistical significance was set a priori at a p-value of 0.05. Age/gender group samples were required to have a minimal size of 50 profiles to be considered for normative analysis. Results indicate an increase in performance in Sway Sports+ modules with age, with scores peaking in the early to mid-20's. Specific tests also show gender-based normative value differences. Thus, Sway Sports+ is ***designed to use both age and gender when relating individual scores to normative values***.

Validity

- VanRavenhorst-Bell et al., 2021[1]: ***This work demonstrated the construct validity of Sway Sports+ Reaction Time, Impulse Control, and Inspection Time modules compared to ImPACT QT***. The sample included 88 healthy adults aged 18 to 48 years (mean 22.09 ± 4.47 years). Participants completed the ImPACT QT battery and Sway Sports+ tests during the same session, and scores from Sway Sports+ were compared to ImPACT QT composite and sub-test scores. The Sway Reaction Time module was statistically significantly correlated ($r = -0.46$ to 0.22, $p \leq 0.05$) with several ImPACT QT reaction time measures. The Sway Impulse Control and Inspection Time measures were also statistically significantly correlated ($r = -0.25$ to -0.46, $p \leq 0.05$) with five ImPACT QT reaction time measures. Overall, these findings suggest that Sway Sports+ cognitive test battery is clinically comparable to the FDA-cleared concussion management system.

- Clark & VanRavenhorst-Bell, 2022[2]: ***This study investigated the construct validity***

of Sway Sports+ in comparison to ImPACT and traditional neurocognitive assessments, including the Wechsler Adult Memory Scale-IV (WMS-IV), Wechsler Adult Intelligence Scale-IV (WAIS-IV), Delis–Kaplan Executive Function System (D-KEFS), and California Verbal Learning Test – 3rd Edition (CVLT-III). A total of 85 adults (mean age 23.1 years; 68% female) participated, with all tests administered by trained professionals in one session. Results indicated significant correlations between Sway Sports+ and both ImPACT and traditional tests, with significance at both $p < 0.001$ and $p < 0.05$. The correlation strength between traditional tests served as a benchmark for the Sway Sports+ assessments, showing that correlations varied from weak (0.20) to strong (0.56), particularly between the WAIS-IV Cancellation and WMS-IV Symbol Search tests. Notably, Sway Sports+ modules exhibited correlation values ranging from 0.22 to 0.42 with traditional tests, while also aligning with ImPACT measures. The Reaction Time module, characterized by rapid cognitive processing, did not correlate significantly with traditional tests, consistent with their differing formats. Moreover, Sway Sports+ demonstrated stronger correlation strengths with traditional neurocognitive tests compared to the correlations observed between ImPACT and these tests. Findings support the utility of Sway Sports+ for cognitive assessments, highlighting its robust associations with both traditional neurocognitive tests and the ImPACT system.

Table 3 – Validity between Sway Sports+ and ImPACT QT & ImPACT

	Sway Reaction Time	Sway Impulse Control	Sway Inspection Time	Sway Memory
ImPACT QT Three Letter Count Correct	0.22	0.17	0.06	---
ImPACT QT Three Letter Time First Click	-0.08	-0.01	-0.17	
ImPACT QT Rectangular Average Time	-0.44	-0.46	-0.19	
ImPACT QT Figure Eight Average Time	-0.46	-0.36	-0.29	
ImPACT QT Complex Average Time	-0.32	-0.31	-0.20	
ImPACT QT Symbol Match Correct Visible	-0.27	-0.19	0.04	
ImPACT QT Symbol Match Correct Hidden	-0.35	-0.06	-0.05	
ImPACT QT Symbol Match Incorrect Hidden	-0.32	-0.10	-0.25	
ImPACT Visual Motor Composite Scale	r_s = 0.26 p = 0.015 *	r_s = 0.43 p < 0.001 *	---	---
ImPACT Reaction Time Composite Scale	r_s = -0.31 p = 0.005 *	r_s = -0.41 p < 0.001 *		
ImPACT Memory Composite Verbal	---	---	---	r_s = 0.13 p = 0.251
ImPACT Memory Composite Visual				r_s = 0.26 p = 0.015 *
ImPACT Design Memory				r_s = 0.24 p = 0.026 *
ImPACT Symbol Match				r_s = -0.22 p = 0.045 *
ImPACT XO Memory				r_s = -0.22 p = 0.046 *

ImPACT Three Letters				r_s = 0.22 p = 0.041 *

Table 4 – Validity between Sway and Traditional Neuropsychological Testing

	Sway Reaction Time	Sway Impulse Control	Sway Memory
WAIS-IV Coding	r_s = 0.13 p = 0.241	r_s = 0.02 p = 0.840	---
WAIS-IV Symbol Search	r_s = 0.07 p = 0.504	r_s = 0.22 p = 0.043 *	
WAIS-IV Cancellation	r_s = 0.10 p = 0.381	r_s = 0.08 p = 0.501	
D-KEFS, Trail Making Condition 1	r_s = 0.09 p = 0.437	r_s = 0.42 p < 0.001 *	
D-KEFS, Trail Making Condition 2	r_s = 0.06 p = 0.437	r_s = 0.20 p = 0.064	
D-KEFS, Trail Making Condition 3	r_s = 0.15 p = 0.170	r_s = 0.33 p = 0.003 *	
WMS-IV Symbol Span	---	---	r_s = 0.00 p = 0.995
WAIS-IV Digit Span			r_s = -0.07 p = 0.542
WAIS-IV Letter-Number Sequencing			r_s = 0.00 p = 0.958
CVLT-III Short Delayed Free Recall			r_s = 0.07 p = 0.551
CVLT-III Short Delayed Cued Recall			r_s = 0.20 p = 0.070

Reliability

- Van Patten et al., 2021[3]: ***This work demonstrated both the inter- and intra-session reliability of Sway Sports+ Reaction Time, Impulse Control, Inspection Time, and Memory modules***. Participants were assessed remotely over 3 subsequent weeks. The mean age of the sample was 26.69 years (± 9.89; range = 18-58). Of the 55 adults in the sample, 69% were women and 89% used an iPhone. ANOVA results indicated non-significant differences in scores across all three weeks for all measures. ICC values for weeks 1-2 ranged from 0.60 to 0.8, and ICC values for weeks 1-3 ranged from 0.68 to 0.88, indicating adequate or better test-retest reliability for all tested measures. The authors also established reliable change estimates for the included Sway Sports+ modules.

- Caccese et al., 2022[4]: ***This work demonstrated inter- and intra-session reliability for Sway Sports+ Balance module using the same sample and test procedure as*** Van Patten et al., 2021***.*** Participants were assessed remotely over 3 subsequent weeks. The sample included 55 healthy adults (69% women) with a mean age of 26.69 years (SD = 9.89; range = 18-58). The ICC for Weeks 1 & 2 was 0.82, and the ICC for Weeks 1 & 3 was 0.88. ANOVA demonstrated no significant differences between test dates, demonstrating strong reliability between test and retest sessions. The authors also established reliable change estimates for the Sway Sports+ Balance module.

- ***An additional study was undertaken that evaluated the test-retest reliability of the Sway Sports+ battery in a sample of healthy adults aged 18-35.*** This

research included detailed method agreement analyses and established reliable change estimates relevant to the clinical interpretation of test score fluctuations. A total of 97 participants were initially recruited, with 56 completing all test and retest sessions, with a one-week interval. Converging evidence from paired sample comparisons, intraclass correlation coefficients (ICCs), Bland-Altman plots, and Deming regression analyses indicate no statistically significant differences in scores between test and retest sessions for any Sway Sports+ module. ICC values ranged between 0.82 and 0.92. This research demonstrates the reliability of the Sway Sports+ test battery and offers critical insights into the interpretation of score changes associated with external events, thus reinforcing the clinical utility of Sway Sports+ in assessing cognitive and functional performance.

- ***An additional study was undertaken that investigated the test-retest reliability of the Sway Sports+ test battery among concussed individuals***, building on prior research that established reliability in healthy adults. Given the challenges in conducting an exact replication of baseline assessments due to variability in post-concussion recovery trajectories, a within-session design was employed. Participants completed multiple trials across different test modules during both baseline and post-concussion assessment sessions. The findings revealed that the Sway Sports+ battery maintains a robust level of reliability during post-concussion testing, comparable to that observed in baseline evaluations. This study utilized a dataset derived from NCAA member schools, ensuring that clinical standards for concussion diagnosis were strictly followed according to NCAA Concussion Safety Protocol guidelines. The results support the application of the Sway Sports+ system as a reliable tool for concussion assessment, contributing to enhanced understanding and management of concussion outcomes in sports.

Table 5 – Test-Retest Reliability of the Sway Sports+ Test Battery

	ICC – 1 week interval *(published, Van Patten et al., 2021 & Caccese et al., 2022)*	**ICC** – 1 week interval *(510(k) submission studies)*
Sway Reaction Time	0.83	0.88
Sway Impulse Control	0.68	0.88
Sway Inspection Time	0.75	0.82
Sway Memory	0.88	0.83
Sway Balance	0.82	0.92

Sensitivity & Specificity

- Chikar & Curtiss, 2023[5]: ***This study evaluated the effectiveness of Sway Sports+ in classifying individuals with sports-related concussions, demonstrating comparable performance to the ImPACT tool.*** Presented at the Big Sky Sports Medicine Conference in Big Sky, MT (Jan 29 – Feb 2, 2023), the research utilized data from athletic organizations that conducted both ImPACT and Sway assessments on athletes with confirmed concussions between November 2020 and October 2022. Participants included 46 athletes (mean age 19.6, SD=1.4; 59% male) who completed pre-season baseline and post-injury testing with both tools. The mean interval between injury and post-injury Sway testing was 1.1

days (SD=1.4). While not all schools provided exact timings for ImPACT post-injury tests, they were administered within a week post-injury. Results indicated that Sway testing achieved a sensitivity of 69.6% (32/46) for predicting concussion group membership, outperforming ImPACT, which showed a sensitivity of 58.7% (27/46) at an 80% confidence interval. A McNemar's test revealed no significant difference between these sensitivities (p=0.383). Notably, the sensitivity and specificity of Sway Sports+ tests are strong overall, although they diminish when analyzing individual modules. This research emphasizes the necessity for multi-modal assessments in concussion evaluation and treatment, consistent with the Sway Sports+ test battery.

- ***An additional study was undertaken that evaluated the effectiveness of the Sway Sports+ test battery in distinguishing between concussed and non-concussed individuals***. The sensitivity and specificity of the Sway Sports+ system were assessed based on score changes from initial baseline to subsequent evaluations. Results indicate high sensitivity but moderate specificity, with high negative predictive values (NPVs) and low positive predictive values (PPVs). While the Sway Sports+ system is effective in detecting concussion effects, the moderate specificity suggests a tendency to over-identify concussed individuals, leading to potential false positives. Nevertheless, in a clinical context where Sway is utilized as part of a comprehensive evaluation by healthcare professionals, such false positives can be eliminated. Importantly, the system demonstrates a very low rate of false negatives, thereby mitigating the risk of untreated concussion cases. The findings underscore the utility of Sway Sports+ in concussion management protocols while highlighting areas for further refinement in specificity.

- ***An additional pilot study was conducted to compare the effectiveness of ImPACT and Sway in the evaluation and management of sports-related concussions in student-athletes***. The research involved 24 high school and college-aged participants who underwent baseline and post-injury testing with both tools. This study documented 47 synchronous testing sessions post-concussion (i.e., ImPACT and Sway testing on the same day) and reported concordance rates of 59.6% between the two tools, with discordance rates of 40.4%. Concordance was seen in both flagged and non-flagged scores. ImPACT identified more abnormal results, suggesting greater sensitivity, while SWAY provided critical measures that were missing in ImPACT. On average, recovery to baseline scores occurred in 12.7 days with ImPACT and 9.9 days with SWAY. While the findings support the complementary use of both tools, the limitations include a small sample size and differences in the functional domains assessed. This study underscores the importance of combining objective digital tools to enhance concussion evaluation and management in clinical and athletic settings.

Conclusion: Sway Sports+ falls within the type of device regulated under 21 CFR §882.1471, Computerized Cognitive Assessment Aid for Concussion (product code POM). The differences between Sway Sports+, the predicate device ImPACT QT, and the reference device ImPACT, described above, do not affect the safety or effectiveness of Sway Sports+ for its intended use. The safety and effectiveness of Sway Sports+ have been demonstrated through software verification and validation, non-clinical assessments, and clinical performance testing. Therefore, Sway Sports+ is substantially equivalent to the predicate device.

References:

1. Vanravenhorst-Bell, H. A., Muzeau, M. A., Luinstra, L., Goering, J. & Amick, R. Z. Accuracy of the SWAY Mobile Cognitive Assessment Application. *Int J Sports Phys Ther* 16, 991 (2021).
2. Clark, C. B. & Vanravenhorst-Bell, H. A. *Construct Validity of Sway Mobile Application Cognitive Testing*. (2022).
3. Van Patten, R., Iverson, G. L., Muzeau, M. A. & VanRavenhorst-Bell, H. A. Test-Retest Reliability and Reliable Change Estimates for Four Mobile Cognitive Tests Administered Virtually in Community-Dwelling Adults. *Front Psychol* 12, (2021).
4. Caccese, J. B. *et al.* Test-Retest reliability and preliminary reliable change estimates for Sway Balance tests administered remotely in community-dwelling adults. *Front Digit Health* 4, 217 (2022).
5. Chikar, J. & Curtiss, C. The Use of the Sway Medical Mobile Application in Concussion Management. in *Big Sky Athletic Training & Sports Medicine Conference* (2023).