September 16, 2023

ImPACT Applications, Inc.
Michael Zagorski
Director of Regulatory Affairs
2140 Norcor Ave., Suite 115
Coralville, Iowa 52241

Re: K231688
Trade/Device Name: ImPACT Version 4
Regulation Number: 21 CFR 882.1471
Regulation Name: Computerized cognitive assessment aid for concussion
Regulatory Class: Class II
Product Code: POM
Dated: August 17, 2023
Received: August 17, 2023

Dear Michael Zagorski:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231688

Device Name
ImPACT Version 4

Indications for Use *(Describe)*
ImPACT is intended for use as a computer-based neurocognitive test battery to aid in the assessment and management of concussion.

ImPACT is a neurocognitive test battery that provides healthcare professionals with objective measure of neurocognitive functioning as an assessment aid and in the management of concussion in individuals ages 12-80.

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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Prepared Date: June 08, 2023

Submitter Information:

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Device Information:

Trade Name:	ImPACT® Version 4
Classification Name:	Computerized cognitive assessment aid for concussion
Device Classification:	Class II
Product Code:	POM, 21 CFR 882.1471
Panel:	Neurology

Predicate Device: ImPACT, K202485

Reason for submission: Device Modifications

Indications for Use:

ImPACT Version 4 is intended for use as a computer-based neurocognitive test battery to aid in the assessment and management of concussion. ImPACT Version 4 is a neurocognitive test battery that provides healthcare professionals with objective measure of neurocognitive functioning as an assessment aid and in the management of concussion in individuals ages 12-80.

Device Description:

ImPACT® (Immediate Post-Concussion Assessment and Cognitive Testing) is a computer-based neurocognitive test battery that allows healthcare professionals to conduct a series of tests on individuals to gather data related to the neurocognitive functioning of the test subject. This test battery measures various aspects of neurocognitive functioning including reaction time, memory, attention, spatial processing speed, and records symptoms of a test subject. ImPACT Version 4 is similar to the paper-and-pencil neuropsychological tests that have long been used by psychologists to evaluate cognition, attention, and memory related to a wide variety of disabilities.

The device is not intended to provide a direct diagnosis or a return-to-activity recommendation, it does not directly manage or provide any treatment recommendations, and any interpretation of the results should be made only by qualified healthcare professional. The neurocognitive assessment represents only one aspect of assisting healthcare professionals in evaluating and managing individuals with cognitive function impairment related to TBI (concussion).

Device Modifications:

The New Device, ImPACT Version 4, is substantially equivalent to the Predicate Device (ImPACT Version 4) cleared under K202485. Both devices have the same intended use as a computerized neurocognitive test to aid in the assessment and management of concussion. They are also identical in terms of technological characteristics as both are stand-alone software applications using a general-purpose computing platform to electronically record objective performance measurements (speed and accuracy) as the test taker responds to stimuli presented on the screen via input devices. Further, there are no changes to the functionality or to the design of the neurocognitive test battery; all tasks, stimuli, and captured information remain identical to the predicate.

There are no changes to the intended use, use environment characteristics, or the conditions assessed.

The differences between the new device and the predicate include:

1. normative database for iPad for ages 12-59;
2. minor software modifications to support use of touchscreen devices, to improve maintainability, cybersecurity and enhance user experience.

Table 1. Predicate Comparison.

Characteristic	Predicate Device: ImPACT Version 4 (K202485)	Reference Device: ImPACT Quick Test (K170551)	New Device: ImPACT Version 4 (rev 4.1)
Intended Use	ImPACT Version 4 is intended for use as a computer-based neurocognitive test battery to aid in the assessment and management of concussion. ImPACT Version 4 is a neurocognitive test battery that provides healthcare professionals with objective measure of neurocognitive functioning as an assessment aid and in the management of concussion in individuals ages 12-80.	ImPACT Quick Test is intended for use as a computerized cognitive test to aid in the assessment and management of concussion in individuals ages 12-70.	**Same as Predicate Device**
Patient Population	12-80	**12-70**	**Same as Predicate Device**
Use Environment	Unsupervised and supervised environment for baseline testing. Supervised environment only for post-injury testing.	Supervised environment only for post-injury testing.	**Same as Predicate Device**
Neurocognitive test battery	1. Demographic data, (age, gender, concussion history, relevant medical information) 2. Symptoms list and questionnaires 3. Neurocognitive test battery consisting of 6 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	1. Basic Demographic data, (age, gender) 2. Observed Signs and Reported Symptoms list 3. Neurocognitive test consisting of 3 modules: ○ Module 1: Symbol Match ○ Module 2: Three Letters ○ Module 3: Eye Tracker	**Same as Predicate Device**
Results	1. Recording and scoring of symptoms 2. Raw Scores, Composite Scores, and validity supporting indexes. 3. Normative data	1. Recording and scoring of symptoms 2. Composite Scores 3. Normative data	**Equivalent.** **Added normative database for tests taken on an iPad**

Suggest options or treatment	No	No	**Same as predicate**
Platform	Stand-alone software running on general purpose commercial off-the-shelf personal computers (desktops, laptops), with a modern web browser connected to the internet.	Apple iPad	**Equivalent. The new device adds option to administer the test on an iPad.**
Software Technology	Software application, written in HTML5, accessed via standard web browser	Software application native to iPadOS	**Equivalent. On an iPad, the test can be accessed through a web browser (like the predicate) or native iPadOS application**
Stimulus presentation	Information and stimulus displayed on a desktop or laptop computer screen	Information and stimulus displayed on an iPad	**New device adds option to use iPad (stimulus displayed on iPad screen)**
Stimulus capture (test taker response)	Device uses computer peripherals to capture te taker's response	Device uses iPad touchscreen to capture test taker's response	**Equivalent. New device captures responses via touchscreen**
Data Storage	Remote central database	Remote central database	**Same as predicate**
Standards Used	ISO 14971 and IEC 62304	ISO 14971 and IEC 62304	**Same as predicate**

Summary of Performance Testing:

Software Verification and Validation.
ImPACT Version 4 software was developed, validated, and documented in accordance with IEC 62304 and FDA Guidance "General Principles of Software Validation." Software verification and validation activities including code reviews, design reviews, evaluations, analyses, traceability assessment, and manual testing were performed in accordance with standards and guidance documents to demonstrate device performance and functionality. All tests met the required acceptance criteria:

- Code reviews: peer review of all modified code performed by software developers.
- Walkthroughs and design reviews of mock-ups and prototypes by a cross-functional team including Developers, Quality Assurance, Regulatory Affairs function, Clinical experts, Company Management, and other stakeholders.
- Software Verification and Validation testing including automated and manual testing.
- Regression Testing: Comprehensive end-to-end testing of the test battery to verify that the modifications did not affect the existing functionality.

Risk Management:
Risk Management activities were conducted in accordance on ISO 14971 assure that all risk related to use of computerized neurocognitive test, including use related risks and cybersecurity risks, are appropriately controlled. All control measures were verified and found to be effective. All individual and overall residual risk is acceptable. The new device has the same safety characteristics as the Predicate Device and same risk profile.

Clinical Data:
The 510(k) included the results of clinical studies. The results of these studies demonstrate the New Device provides a reliable measure of cognitive function to aid in assessment and management of concussion and is therefore substantially equivalent to the Predicate Device.

To support the test administration on iPad and to provide a normative database, a prospective clinical investigation was conducted to collect data to: (i) standardize the test and construct the normative database for tests performed on iPad; and (ii) demonstrate test-retest reliability.

i. Standardization and Normative sample

The normative sample 1495 subjects ages 12-59 (670 males, 825 females) was collected prospectively from 4 different sites with study participants across the US. Data collection took place in 2022 and 2023. The sites were approved to collected data by two ethics boards, Advarra IRB Services (for supervised testing) and St. Joseph's University in Philadelphia (for unsupervised remote testing). All subjects met the-appropriate inclusion criteria, which are the same as those used for creating normative tables for the mouse and trackpad in the predicate device. Data for the new sample was conducted in mixed environment including supervised and unsupervised testing to best approximate the real-world performance.

All subjects had to meet the following inclusion criteria to be eligible: (i) test administered on iPad; (ii) age: 12-59; (iii) primary English speaking or fluent in English; (iv) not suffering from a concussion or being treated for a concussion in the past 6 months; (v) no known physical, neurological, behavioral or psychological impairment that would affect their ability to perform the test; (vi) hearing or vision impairments that have been corrected outside of normal limits (e.g. prescription glasses, hearing aid), and (vii) a signed IRB approved consent form.

ii. Test-retest Reliability

Over the years, there have been a sizeable body of literature that has documented the reliability of ImPACT. In general, ImPACT has been found to be highly reliable across time. As the items of the test and the six modules have not changed, this literature is relevant to this version of ImPACT as well as all previous version (predicates). Summary of these studies is provided in the device labeling.

The test-retest reliability was also calculated in a sample of participants using the iPad version of the test. Test takers were 116 individuals ages 12-59 from the standardization sample who completed an initial baseline assessment using an iPad, and a second baseline with a between test interval ranging of 7 to 21 days (mean=12.7 days, SD=4.3 days). Test-takers were 40 males (34.5%, mean age 26.6, SD=14.2 years) and 76 females (65.5%, mean age 28.9, SD=14.4 years), with no significant age difference between based on gender (p=.40). Test-retest reliability was calculated Pearson's Product-Moment Correlation coefficients as well as intra-class correlation coefficients (ICCs) for the ImPACT Composite Scores as well as Two Factor Scores. Pearson's correlations and ICCs are consistent with those from the test-retest coefficients obtained using Mouse and Trackpad inputs of the predicate device.

Substantial Equivalence Conclusion:

The differences between the two devices described above do not affect the safety or effectiveness of ImPACT Version 4.1 for its intended use and do not raise new questions of safety and effectiveness, which was demonstrated through risk management and performance testing including software verification and validation, clinical investigations and non-clinical analytical assessments. Therefore, ImPACT Version 4.1 is substantially equivalent to the Predicate Device.