December 25, 2020

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

Re: K202485
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 28, 2020
Received: August 31, 2020

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,

For 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)*
K202485

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 measures 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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Submission Date: August 28, 2020

Submitter Information:

Company: ImPACT Applications, Inc.
2140 Norcor Ave., Suite 115
Coralville, IA 52241

Contract Person: Michael Zagorski
Director of Regulatory Affairs
ImPACT Applications, Inc.
Tel: 412-567-8400 ext. 939
Email: mzagorski@impacttest.com

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, K181223

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 3.3.0) cleared under K181223. 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 device.

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. applicable age range for the test has been extended to 80 years (the new age range is 12-80);
2. normative database has been updated on a new sample and separate normative calculations were provided for mouse and trackpad;
3. changes to device output:
    - addition of a new output score called Two-Factor Score to assist with the interpretation of results;
    - modification to the Invalidity Indicator calculations based on the new normative data set; and
    - removal of the CEI (cognitive efficiency index);
4. minor software modifications to improve maintainability, cybersecurity and enhance user experience.

Table 1. Predicate Comparison.

Characteristic	Predicate Device: ImPACT (K181223)	Modified Device: ImPACT Version 4
Intended Use	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 12-59.	**Same intended use** **Modified indications - age range of the patient population was extended to 80.**
Patient Population	12-59	**Different from predicate.** **New age range is 12-80**
Use Environment	Unsupervised and supervised environment for baseline testing. Supervised environment only for post-injury testing.	**Same as predicate**
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: o Module 1: Word Memory and Delayed Memory Recognition o Module 2: Design Memory and Delayed Design Recognition o Module 3: X's and O's o Module 4: Symbol Matching o Module 5: Color Match o Module 6: Three Letter Memory	**Same as predicate**
Results	1. Recording and scoring of symptoms 2. Raw Scores, Composite Scores, and validity supporting indexes. 3. Normative data	**Similar to predicate.**

		New data used to construct the normative database with separate data sets for mouse and trackpad A new Two-Factor Score.
Suggest options or treatment	No	**Same as predicate**
User Interface	Desktop or laptop computer screen to present stimuli.	**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.	**Same as predicate**
Software Technology	Software application, written in HTML5, accessed via standard web browser	**Same as predicate**
Stimulus presentation	Information and stimulus displayed on a desktop or laptop computer screen	**Same as predicate**
Stimulus capture (test taker response)	ImPACT uses computer peripherals to capture test taker's response	**Same as predicate**
Data Storage	Remote central database	**Same as predicate**
Standards Used	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 virtually the same safety characteristics as the Predicate Device and same risk profile.

Clinical Data:
The 510(k) included the results of clinical studies that examined the validity of ImPACT Version 4 by documenting correlations with traditional neuropsychological tests. Clinical data was also collected to examine test-retest reliability and to construct a normative database.
The results of these studies demonstrate ImPACT Version 4 provides a reliable measure of cognitive function to

aid in assessment and management of concussion and is therefore substantially equivalent to the Predicate Device.

For the construction of the normative database for the 12-59 age range, de-identified data of 71,815 subjects were selected from Company test database of 766,093. Subjects were selected based on age, gender, type of input device they used to complete the test (i.e., computer mouse versus trackpad), spoke English as a primary language, completed a baseline test in English, and were from the United States of America. Further, in order to ensure subjects were not experiencing post-concussion symptoms or chronic effects of neurological disorders, all subjects reported as not having sustained a concussion in the 6 months prior to testing and had no other neurological issues that would affect performance (e.g., history of epilepsy, meningitis, brain surgery or other neurological disease). In addition, all subjects had no reported diagnosis of Attention Deficit Hyperactivity Disorder or Learning Disorder.

For the new age population, ages 60-80, a clinical investigation was conducted to collect data to: (i) standardize the test and construct the normative database for the new age range; (ii) demonstrate test-retest reliability; and (iii) establish Construct Validity.

- Standardization and Normative sample
  The normative sample age 60-80 (554, 174 males, 380 females) was collected from 8 different sites across the United States, including universities, hospitals and clinics, and private medical practices. Data collection began in 2017 and ended in 2020. All sites were IRB approved with oversight from Advarra IRB services. All subjects had to meet the following inclusion criteria to be eligible: (i) age: 60-80; (ii) primary English speaking or fluent in English; (iii) not a resident in a skilled nursing facility; (iv) not suffering from a concussion or being treated for a concussion; (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 within normal limits; (vii) a score of 24 or greater on the Mini-Metal State Examination (MMSE); and (viii) a signed IRB approved consent form.
- Test-retest Reliability
  A subset of participants from the normative extension sample described above, ages 60-80 (mean age of 68.18, SD=5.1 years), completed two ImPACT assessments across an average range of 30 days (mean=16.04 days, S.D. = 8.65 days). The sample consisted of a total of 93 individuals (64.5% females, 35.5% males). Using Reliable Change Indices (RCIs), only a small percentage of participants' scores showed reliable or "significant" change on the composite scores (0%-1%), or factor scores (0%-2%). These results suggest the cognitive performance of test takers at baseline remained stable over a one-month period.
- Construct Validity
  To determine whether ImPACT Version 4 correlates significantly with a widely utilized and previously validated instrument of Memory and Motor Speed, select subtests of the HVLT, BVMT-R, SDMT, and ImPACT were administered within the same session. The sample was composed of 71 individuals between the ages of 60 and 80 (mean age of 67.27 years, S.D. 4.92 years) and 63.4% females and 36.6% males. All measures were administered by Neuropsychologists trained in test administration as part of the study to collect data for normative dataset described above. ImPACT Verbal and Visual Memory Composite scores correlate with both the HVLT and BVMT-R, as well as the SDMT Memory Sub-scales (significant at P<.001) which represent measures of verbal and visual memory. ImPACT Motor Speed and Reaction Time Composite Scores both correlate with the SDMT Total Correct Subscales, which represents a measure of psychomotor coding speed.

Substantial Equivalence Conclusion:

The differences between the two devices described above do not affect the safety or effectiveness of ImPACT Version 4 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 is substantially equivalent to the Predicate Device.