October 20, 2018

ImPACT Applications, Inc.
Michael Zagorski
Director of Regulatory Affairs
9665 Granite Ridge Drive, Suite 550
San Diego, California 92123

Re: K181223
Trade/Device Name: ImPACT
Regulation Number: 21 CFR 882.1471
Regulation Name: Computerized Cognitive Assessment Aid For Concussion
Regulatory Class: Class II
Product Code: POM
Dated: June 27, 2018
Received: June 29, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

For Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181223

Device Name
ImPACT

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 12-59.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Submission Date: September 19, 2018

Submitter Information:

Company: ImPACT Applications, Inc.
9665 Granite Ridge Drive, Suite 550
San Diego, CA 92123

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®
Common Name:	Computerized Cognitive Test
Classification Name:	Computerized cognitive assessment aid for concussion
Device Classification:	Class II
Product Code:	POM, 21 CFR 882.1471
Panel:	Neurology
Predicate Device:	ImPACT, K170209
Reason for submission	Device Modifications

Indications for 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.

Device Description:
ImPACT® (Immediate Post-Concussion Assessment and Cognitive Testing) is a computer-based neurocognitive test battery.

ImPACT is a software-based tool that allows healthcare professionals to conduct a series of neurocognitive tests on individuals to gather basic data related to the neurocognitive functioning of the test subject. This computerized cognitive test battery evaluates and provides a healthcare professional with measures of various neurocognitive functions, including the reaction time, memory, attention, spatial processing speed and symptoms of an individual.

ImPACT provides healthcare professionals with a set of well-developed and researched neurocognitive tasks that have been medically accepted as state-of-the-art best practices and is intended to be used as part of a multidisciplinary approach to making return to activity decisions.

ImPACT for use in supervised and unsupervised settings incorporates several risk controls to mitigate the risk of external factors affecting the validity of the test results. These include:

- Test structure that assesses several different cognitive domains.
- Subscale scores, composite scores based on factor analysis, and supporting measures (e.g., Invalidity Indicator, Cognitive Efficiency Index, and Reliable Change Index) were all developed and validated to reduce error caused by variation in test environment or effort, and to assist the healthcare provider in interpreting of results.
- An Invalidity Indicator was included to aid in identifying invalid baseline examinations when performance falls below the expected range.
- Baseline test results are not provided to test-takers (the results are only available for viewing by healthcare providers; a unique id, called an ImPACT Passport ID, is assigned to each test allowing the test-takers to share the results with trained healthcare providers).
- Instructions detailing the proper baseline testing environment available to the test taker prior to test purchase and at the beginning of the test. These instructions must be viewed before proceeding to the baseline test.
- A baseline test is not required for clinical assessment of concussion, but provides incremental validity to the management of a suspected concussion when used in conjunction with the normative database available for post-injury testing.

Device Modifications:

The modified version of ImPACT is substantially equivalent to predicate device cleared under K170209. Both devices have the same intended use for use as computerized neurocognitive tests 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 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, functionality of both devices is identical.

The differences between the new device and the predicate include:

- change to the use environment to allow baseline testing in unsupervised environment, and
- modifications to the optional demographics portion of the test to shorten and streamline the test administration.

There are no changes to the intended use, users, patient population or the conditions assessed. Further, there are no changes to the design of neurocognitive test battery; all tasks, stimuli, and captured information remain identical to the original version.

Table 1. Predicate Comparison.		
Characteristic	**Predicate Device: ImPACT (K170209)**	**Modified Device: ImPACT**
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 as predicate**
Patient Population	12-59	**Same as predicate**
Use Environment	Recommended supervised environment for baseline and post-injury testing.	**Similar to predicate** Unsupervised and supervised environment for baseline testing. Supervised environment only for post-injury testing.
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	**Same as predicate**
Results	1. Recording and scoring of symptoms 2. Raw Scores and Composite Scores 3. Normative data	**Same as predicate**
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 activities including code reviews, design reviews, evaluations, analyses, traceability assessment, and manual testing were performed in accordance with IEC 62304 and other software standards to demonstrate device performance and functionality. All tests met the required acceptance criteria. Risk Management activities conducted in accordance with ISO 14971 assure all risk related to use of a computerized neurocognitive test, including use related risks and security risks, are appropriately mitigated.

Additionally, to validate test takers' ability to perform the baseline test in an unsupervised environment, a usability assessment and a usability study was performed on 162 subjects. The sample included 74 college students, 44 Middle and High School students, and 44 adults. 5.8% of subjects reported invalid results. The results of the studies indicate that the number of invalid self-administered tests are not different when compared to the supervised environment reported in the literature.

Summary of Clinical Data:

The goal of this is to demonstrate that performing a baseline test does without direct oversight of a baseline test administrator does not affect the test-retest reliability of ImPACT.

A total of 50 participants completed the ImPACT test and brief survey on two occasions, approximately 80 days between assessments (Mean=80 days, S.D.=17 days, Range=52 to 108 days). None of the participants were unable to complete the test independently, or in one test session, with no "Invalid Baselines" obtained.

Pearson correlations between baseline assessments ranged from .43 to .78. ICCs reflected higher reliability than Pearson's r, across all measures. Visual Motor Speed scores showed the most stability (mean ICC=.91, .84 to .95 (lower and upper 95% confidence intervals); UER=.91), followed by Reaction Time (.78, .61-.87; UER=.79), Visual Memory (.62, .34-.77; UER=.64), and Verbal Memory (.55, .20-.74; UER=.56). Mean ImPACT composite and symptom scores showed no significant improvement between the two assessments on any of the Composite Scores. There were no significant practice effects across the two assessments, at a mean of 80 days, and scores reflected considerable stability as reflected in ICCs and UERs.

Substantial Equivalence:

The differences in the use environment and software described above do not affect the safety or effectiveness of ImPACT for its intended use, which was demonstrated through risk management, usability assessment and performance testing. Therefore, the modified device is substantially equivalent to the predicate.