DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 21, 2017

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

Re: K170551
Trade/Device Name: ImPACT Quick Test
Regulation Number: 21 CFR 882.1471
Regulation Name: Computerized Cognitive Assessment Aid For Concussion
Regulatory Class: Class II
Product Code: POM
Dated: May 22, 2017
Received: May 23, 2017

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170551

Device Name
ImPACT Quick Test

Indications for Use *(Describe)*
ImPACT Quick Test is intended for use as a computerized cognitive test aid in the assessment and management of concussion in individuals ages 12-70.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Section 5 – 510(k) Summary

Submission Date: May 22, 2017

Submitter Information:

Company: ImPACT Applications, Inc.
9665 Granite Ridge Drive, Suite 150
San Diego, CA 92123

Official Correspondent: Michael Zagorski
Director of Regulatory Affairs
ImPACT Applications, Inc.
Tel: 412-567-8400 x.939
Email: mzagorski@impacttest.com

Device Information:

Trade Name:	ImPACT Quick Test™
Classification Name:	Computerized Cognitive Assessment Aid for Concussion
Device Class:	II
Device Classification:	21 CFR 882.1471, Product Code POM
Review Panel	Neurology

Predicate Device: ImPACT (DEN150037)

Indications for Use:
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

Device Description:
ImPACT Quick Test (ImPACT) QT is a brief computerized neurocognitive test designed to assist trained healthcare professionals in determining a patient's status after a suspected concussion. ImPACT QT provides basic data related to neurocognitive functioning, including working memory, processing speed, reaction time, and symptom recording.

ImPACT QT is designed to be a brief 5-7 minute iPad-based test to aid sideline personnel and first responders in determining if an athlete/individual is in need of further evaluation or is able to immediately return to activity. ImPACT QT is not a substitute for a full neuropsychological evaluation or a more comprehensive computerized neurocognitive test (such as ImPACT).

Comparison to Predicate Device:

ImPACT QT is substantially equivalent to ImPACT, manufactured by ImPACT Applications, Inc., and cleared under DEN150037. ImPACT QT and Predicate Device ImPACT share the same intended use as Computerized Cognitive Assessment Aid for Concussion. Both devices enable administration of neuropsychological tests to evaluate a test taker's cognitive state. They are also similar in terms of technological characteristics as both administer neurocognitive test modules on a standard off-the-shelf computing device and record objective cognitive performance measurements as the test taker responds to stimuli presented on the screen.

ImPACT QT differs from Predicate Device in the content and design of the cognitive tasks, and the test results reported for analysis, including different normative data set.

Table 1 – Substantial Equivalence Comparison

Characteristic	New Device: ImPACT Quick Test	Predicate Device: ImPACT (DEN150037)	Reference Device: ImPACT Pediatric (DEN150037)
Indications of Use	**Similar to the Predicate and the Reference Device.** ImPACT QT is intended for use as a computerized cognitive test to aid in the assessment and management of concussion in individuals ages 12-70.	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.	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 5-11.
Patient Population	**Similar to the Predicate** ImPACT QT age range is 12-70	12-59	5-11
Technology	**Similar to Predicate**, and the same as Reference Device.	Stand-alone software application delivered on desktop/laptop computers	Stand-alone software application delivered on iPad
Neurocognitive tasks administered	Similar to Predicate and Reference Devices **ImPACT QT includes:** • Demographic data, (age, gender); • Symptoms list; • Neurocognitive test battery consisting of 3 modules: ○ Module 1: Symbol Match ○ Module 2: Three letter memory ○ Module 3: Attention Tracker Modules 1 and 2 are identical to Modules 3 and 4 of the Predicate Device.	1. Demographic data, (age, gender, concussion history); 2. Symptoms list; 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. Demographic data, (age, gender, concussion history); 2. Symptoms list; 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: Stop and Go ○ Module 4: Memory Touch ○ Module 5: Picture Match ○ Module 6: Color Match

Reporting	**Similar to Predicate and Reference Devices.** The new device reports symptoms and displays test results in a form of composites score percentiles based on normative data.	• Symptom scores • Raw Scores (subscales) • Composite scores with percentiles based on normative data. • Reliable Change Index.	• Symptom scores • Raw Scores • Factor Scores with percentiles based on normative data.
Results Interpretation	**Same as Predicate and Reference Devices.**	ImPACT does not provide a recommendation that the patient is impaired vs. unimpaired. Clinical interpretation of the results includes comparison with the normative database.	ImPACT Pediatric does not provide a recommendation that the patient is impaired vs. unimpaired. Clinical interpretation of the results includes comparison with the normative database.
Stimulus presentation	**Same as Predicate Device**	Computer screen	Tablet (mobile device) screen
Test taker response capture	**Same as Reference Device**	Computer mouse or keyboard	User input (finger touch) via tablet touch-screen
Psychometric properties	**Same as Predicate and Reference Devices**	Demonstrates construct validity with traditional neuropsychological tests and test-retest reliability.	Demonstrates construct validity with traditional neuropsychological tests and test-retest reliability.
Standards used	ISO 14971 IEC 62304	ISO 14971 IEC 62304	ISO 14971 IEC 62304

Summary of Non-Clinical Testing:

ImPACT QT 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 software testing were executed to demonstrate device performance and functionality. All activities were completed successfully and met the required acceptance criteria.

Risk Management activities, conducted in accordance on ISO 14971, assure that all risks related to use of a computerized neurocognitive test, including use related risks and cybersecurity risks, are appropriately mitigated.

Summary of Clinical Testing:

The 510(k) included the results of clinical studies that examined the construct and concurrent validity of ImPACT QT as a clinical tool by documenting correlations with ImPACT and traditional neuropsychological tests. Clinical data was also collected to examine test-retest reliability and to construct a normative database.

Normative Database:

To develop a normative data set, 772 subjects were recruited by utilizing 11 sites across the United States. All subjects completed an IRB approved consent form and met eligibility criteria before testing. The standardization sample was developed to be representative of the population of individuals ages 12-70 years, based upon the 2010 U.S. Census, approximating the targets for age, gender and race.

All subjects completed an IRB approved consent form and met eligibility criteria before testing.

All testing was completed by professionals who were specifically trained to administer the test. These professionals consisted of neuropsychologists, physicians, psychologists, neuropsychology/psychology graduate students, certified athletic trainers and athletic training graduate students. All testing was completed in a supervised setting.

Concurrent Validity

A study was completed comparing ImPACT Quick Test to ImPACT, the test from which it was derived. This study compared 92 subjects who were given both ImPACT and ImPACT Quick Test. Tests were administered in counterbalanced order across subjects by trained examiners. The sample consisted of 41 (45%) males and 51 (55%) females with an average age of 36.5 years (S.D. = 19.8 years, range = 12-76 years).

The correlations between the two instruments tend to be in the moderate to high range, 0.32-0.63. This suggests that although the two instruments measure similar constructs, the fact that ImPACT Quick Test contains a subset of ImPACT tests as well as unique content explains the moderate relationship between the two instruments.

Table 2. Concurrent Validity Between ImPACT and ImPACT Quick Test.	
Visual Motor Speed	
Three Letters Counting Average Correct	.63
Reaction Time	
Three Letters Average Time First Click	.47
Attention Tracker Rectangular Average Time Correct	.44
Attention Tracker Figure Eight Average Time Correct	.40
Attention Tracker Complex Average Time Correct	.43
Symbol Match Correct Visible Average Answer Time	.61
Symbol Match Correct Hidden Average Answer Time	.36
Symbol Match Incorrect Hidden Average Answer Time	.32
All correlations p<.001	

The results of these studies demonstrate that ImPACT QT provides a reliable measure of cognitive function to aid in assessment of concussion, and is therefore substantially equivalent to the Predicate Device.

Construct Validity

A study was completed comparing ImPACT Quick Test to the Brief Visuospatial Motor Test (BVMT-R) (Benedict, 1997), a measure of visual-spatial memory, the Color Trails Test (CTT) (D'Elia et al., 1998), a measure of attention and sequencing, and the Symbol Digit Modalities Test (SDMT) (Smith, 1973), a measure of attention, visual scanning and motor speed).
The study compared the results of 118 subjects; the tests were administered in counterbalanced order across subjects by trained examiners. The sample consisted of 73 (62%) females and 45 (38%) males with an average age of 32.5 years (S.D. = 16.7 years, range = 18-79 years).

The results suggest that Attention Tracker and Motor Speed correlate more highly with the BVMT-R, and CTT, than does the Memory Scale. These results are consistent with what one would expect as the BVMT-R, and CTT, provide measures of attention and motor speed. Although the correlation between the Memory Scale and the BVMT-R, was lower than expected, the fact that the format and task demands are significantly different can explain the lower than expected correlations.

Table 3 - Construct validity: correlation of ImPACT Quick Test and neuropsychological test measures								
Attention Tracker	**r**	**Sig r**	**Motor Speed**	**r**	**Sig r**	**Memory**	**r**	**Sig r**
BVMT-R Trial 1	29	.07	BVMT-R Trial 1	.32	.001	BVMT-R Trial 1	.10	.30
BVMT-R Trial 2	.05	.58	BVMT-R Trial 2	.18	.05	BVMT-R Trial 2	.14	.14
BVMT-R Trial 3	-.01	.93	BVMT-R Trial 3	.17	.06	BVMT-R Trial 3	.13	.16
BVMT-R Total Score	.10	.27	BVMT-R Total Score	.30	.001	BVMT-R Total Score	.13	.16
Color Trails-R Trial 1 Time	.37	.001	Color Trails-R Trial 1 Time	.50	.001	Color Trails-R Trial 1 Time	.03	.75
Color Trails-R Trial 2 Time	.28	.003	Color Trails-R Trial 2 Time	.61	.001	Color Trails-R Trial 2 Time	.16	.09
Color Trails-S Trial 1 Time	-.35	.05	Color Trails-S Trial 1 Time	.36	.04	Color Trails-S Trial 1 Time	.12	.53
SDMT Correct	.19	.29	SDMT Correct	.20	.28	SDMT Correct	.04	.85
Legend: r=Pearson's correlation coefficient; Sig r=significance r								

Test-Retest Reliability

A sample of 76 individuals were tested twice for this study. During their initial visit, informed consent was obtained from each participant after which they were given ImPACT Quick Test and asked to return to take the test 1-4 weeks in the future. None of the test subjects had a history of concussion within one year of participating in the study and none had concussion symptoms during their participation. No subject was included in the study if he or she had a history of epilepsy or other neurological disorders or were taking psychoactive medication at the time of the study. All testing was completed under the direction of a trained test administrator.

Pearson's Correlations for the Composite scores presented in the table were calculated to examine test-retest reliability for the subtests across the first two test sessions. All test-retest correlations (r) were significant at the p<.001 level or beyond, with the composite score correlations 0.18 for Memory, 0.73 for Attention Tracker, and 0.82 for Motor Speed. With the large majority of the correlations in the .6 to .8 range and the RCI scores total percent change at the various levels, this reflects considerable stability across the re-test period.

Table 4 – Test-retest reliability results for ImPACT Quick Test Composite Scores							
		[a]Reliable Change (RCI)			[b]RCI Total Percent Change		
Composite Scores	**r**	**80% CI**	**90% CI**	**95% CI**	**80% CI**	**90% CI**	**95% CI**
Attention Tracker	.73	△.56/14%/3%	△.72/8%/1%	△.86/5%/1%	17%	9%	6%
Motor Speed	.83	△4.08/14%/5%	△5.22/12%/4%	△6.24/8%/3%	19%	16%	11%
Memory	.18	△3/15%/12%	△4/9%/5%	△5/1%/1%	28%	14%	2%
[a] Reliable Change (RCI) reflects the delta (△) required for "reliable" change, and the percentage of cases declining and improving beyond that delta. [b] Reliable Change Total Percent Change reflects the total percentage of cases falling outside the confidence interval, summing both improvement and decline.							

Conclusion:

ImPACT QT falls within the generic type of device regulated under 21 CFR 882.1471, Computerized Cognitive Assessment Aid for Concussion, Product Code POM. The differences between the two devices described above do not affect either the safety or effectiveness of ImPACT QT for its intended use and do not raise new questions of safety and effectiveness; therefore, ImPACT QT is substantially equivalent to the Predicate Device ImPACT.