DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 23, 2017

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

Re: K170209
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: January 23, 2017
Received: January 24, 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)*
K170209

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.

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Section 5 – 510(k) Summary

Submission Date: January 23, 2016

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®, ImPACT® Workplace
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, DEN150037
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.

Comparison to Predicate Device:

ImPACT (HTML5 Version) is substantially equivalent to ImPACT (Flash version), manufactured by ImPACT Applications, Inc., and cleared under DEN150037. Both devices have the same intended use and indications for use as computerized neurocognitive tests to aid in the assessment and management of concussion. They are also similar 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, all functionality of both devices is identical.

The differences between the new device and the predicate are limited to a modification to the software code language used to develop the device.

Device Modifications

The software of the predicate device, Adobe Flash Rich Internet Application (RIA) written in Adobe ActionScript programming language, was re-written using HTML5/CSS/JavaScript. The rewrite effort preserved all functions of the original version. The changes are preventive, to improve software maintainability, reliability, and adaptability to cope with changes in the software environment. There are no changes to the intended use, indication for use, including users, patient population, environment of use, 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.

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 the effect of the software change on the performance, two laboratory studies (one bench, one in volunteers age 19-22) were conducted to compare the results of the predicate device (Flash code) and the new device for reaction time. The studies showed that the differences in performance are statistically and clinically insignificant.

Substantial Equivalence:

The differences in design described above do not affect the safety or effectiveness of ImPACT for its intended use, functionality or performance, which was demonstrated through performance testing. Therefore, ImPACT (HTML5 version) is substantially equivalent to predicate ImPACT (Flash version).