DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 22, 2016

ImPACT Applications, Inc.
Michael Zagorski
Director, Regulatory Affairs
2000 Technology Drive, Suite 150
Pittsburgh, PA 15219

Re: DEN 150037
ImPACT and ImPACT Pediatric
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 882.1471
Regulation Name: Computerized Cognitive Assessment Aid for Concussion
Regulatory Classification: Class II
Product Code: POM
Dated: July 30, 2015
Received: August 11, 2015

Dear Mr. Zagorski:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the ImPACT and ImPACT Pediatric, prescription devices under 21 CFR 801.109, which are indicated as follows:

ImPACT:
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 Pediatric:
ImPACT Pediatric is intended for use as a computer-based neurocognitive test battery to aid in the assessment and management of concussion.

ImPACT Pediatric 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.

This order, therefore, classifies the ImPACT and ImPACT Pediatric, and substantially equivalent devices of this generic type, into class II under the generic name, Computerized Cognitive Assessment Aid for Concussion.

FDA identifies this generic type of device as:

> **Computerized Cognitive Assessment Aid for Concussion.** The computerized cognitive assessment aid for concussion is a prescription device that uses an individual's score(s) on a battery of cognitive tasks to provide an indication of the current level of cognitive function in response to concussion. The computerized cognitive assessment aid for concussion is used only as an assessment aid in the management of concussion to determine cognitive function for patients after a potential concussive event where other diagnostic tools are available and does not identify the presence or absence of concussion. It is not intended as a stand-alone diagnostic device.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On August 11, 2015, FDA received your *de novo* requesting classification of the ImPACT and ImPACT Pediatric into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the ImPACT and ImPACT Pediatric into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device type for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that ImPACT and ImPACT Pediatric, indicated as follows:

> ***ImPACT:***
> *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 Pediatric:***
> *ImPACT Pediatric is intended for use as a computer-based neurocognitive test battery to aid in the assessment and management of concussion.*

> *ImPACT Pediatric 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.*

can be classified in class II with the establishment of special controls. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measure**
User discomfort (e.g., visual or mental fatigue)	• Labeling
Incorrect result, inclusive of: • False positive – cognitive impairment from concussion when in fact none is present • False negative – cognitive impairment from concussion is not noted when in fact cognitive impairment is present	• Clinical performance testing • Software verification, validation, and hazard analysis • Labeling

In combination with the general controls of the FD&C Act, the Computerized Cognitive Assessment Aid for Concussion is subject to the following special controls:

1. Software, including any proprietary algorithm(s) used by the device to arrive at its interpretation of the patient's cognitive function must be described in detail in the software requirements specification (SRS) and software design specification (SDS). Software verification, validation, and hazard analysis must be performed.

2. Clinical performance data must be provided that demonstrates how the device functions as an interpretation of the current level of cognitive function in an individual that has recently received an injury that causes concern about a possible concussion. The testing must:
    a. Evaluate device output and clinical interpretation.
    b. Evaluate device test-retest reliability of the device output.
    c. Evaluate construct validity of the device cognitive assessments.
    d. Describe the construction of the normative database, which includes the following:
        i. How the clinical work-up was completed to establish a “normal” population, including the establishment of inclusion and exclusion criteria.
        ii. Statistical methods and model assumptions used.

3. The labeling must include:
    a. A summary of any clinical testing conducted to demonstrate how the device functions as an interpretation of the current level of cognitive function in a

patient that has recently received an injury that causes concern about a possible concussion. The summary of testing must include the following:

i. Device output and clinical interpretation.
ii. Device test-retest reliability of the device output.
iii. Construct validity of the device cognitive assessments.
iv. A description of the normative database, which includes the following:
    1. How the clinical work-up was completed to establish a "normal" population, including the establishment of inclusion and exclusion criteria.
    2. How normal values will be reported to the user.
    3. Representative screen shots and reports that will be generated to provide the user results and normative data.
    4. Statistical methods and model assumptions used.
    5. Whether or not the normative database was adjusted due to differences in age and gender.

b. A warning that the device should only be used by healthcare professionals who are trained in concussion management.
c. A warning that the device does not identify the presence or absence of concussion or other clinical diagnoses.
d. A warning that the device is not a stand-alone diagnostic.
e. Any instructions technicians must convey to patients regarding the administration of the test and collection of cognitive test data.

In addition, these are prescription devices and must comply with 21 CFR 801.109. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Computerized Cognitive Assessment Aid for Concussion they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your devices comply with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305),

Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your devices as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Stacie Gutowski, Ph.D. at 240-402-6032.

Sincerely,

Jonette R. Foy -S

Jonette Foy, Ph.D.
Deputy Director
for Engineering and Science Review
Office of Device Evaluation
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