4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA-2015-N-2737]

Medical Devices; Neurological Devices; Classification of the Computerized Cognitive

Assessment Aid for Concussion

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the Computerized

Cognitive Assessment Aid for Concussion into class II (special controls). The special controls

that will apply to the device are identified in this order and will be part of the codified language

for the computerized cognitive assessment aid for concussion's classification. The Agency is

classifying the device into class II (special controls) in order to provide a reasonable assurance of

safety and effectiveness of the device.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL

REGISTER]. The classification was applicable on August 22, 2016.

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SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the

FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May

28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred

to as post-amendments devices, are classified automatically by statute into class III without any

FDA rulemaking process. These devices remain in class III and require premarket approval,

unless and until the device is classified or reclassified into class I or II, or FDA issues an order

finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C

Act, to a predicate device that does not require premarket approval. The Agency determines

whether new devices are substantially equivalent to predicate devices by means of premarket

notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21

CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug

Administration Safety and Innovation Act (Pub. L. 112-144), provides two procedures by which

a person may request FDA to classify a device under the criteria set forth in section 513(a)(1).

Under the first procedure, the person submits a premarket notification under section 510(k) of

the FD&C Act for a device that has not previously been classified and, within 30 days of

receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act,

the person requests a classification under section 513(f)(2). Under the second procedure, rather

than first submitting a premarket notification under section 510(k) of the FD&C Act and then a

request for classification under the first procedure, the person determines that there is no legally

marketed device upon which to base a determination of substantial equivalence and requests a

classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of "low-moderate risk" or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA shall classify the device by written order within 120 days. This classification will be the initial classification of the device.

On August 11, 2015, ImPACT Applications, Inc., submitted a request for classification of the ImPACT and ImPACT Pediatric under section 513(f)(2) of the FD&C Act.

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on August 22, 2016, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 882.1471.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a computerized cognitive assessment aid for concussion will need to comply with the special controls named in this final order. The device is assigned the generic name computerized cognitive assessment aid for concussion, and it is identified as 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.

FDA has identified the following risks to health associated specifically with this type of device, as well as the mitigation measures required to mitigate these risks in table 1.

Table 1.--Computerized Cognitive Assessment Aid for Concussion Risks 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

FDA believes that the special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness.

Computerized cognitive assessment aid for concussion devices are not safe for use except under the supervision of a practitioner licensed by law to direct the use of the device. As such, the device is a prescription device and must satisfy prescription labeling requirements (see 21 CFR 801.109 (Prescription devices)).

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), if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the computerized cognitive assessment aid for concussion they intend to market.

II. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910-0120, and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910-0485.

List of Subjects in 21 CFR Part 882

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882--NEUROLOGICAL DEVICES

1. The authority citation for part 882 is revised to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Add § 882.1471 to subpart B to read as follows:

§ 882.1471 Computerized cognitive assessment aid for concussion.

(a) Identification. 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.

(b) Classification. Class II (special controls). The special controls for this device are:

(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:

(i) Evaluate device output and clinical interpretation.

(ii) Evaluate device test-retest reliability of the device output.

(iii) Evaluate construct validity of the device cognitive assessments.

(iv) Describe the construction of the normative database, which includes the following:

(A) How the clinical workup was completed to establish a "normal" population, including the establishment of inclusion and exclusion criteria.

(B) Statistical methods and model assumptions used.

(3) The labeling must include:

(i) 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:

(A) Device output and clinical interpretation.

(B) Device test-retest reliability of the device output.

(C) Construct validity of the device cognitive assessments.

(D) A description of the normative database, which includes the following:

(1) How the clinical workup 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.

(ii) A warning that the device should only be used by health care professionals who are trained in concussion management.

(iii) A warning that the device does not identify the presence or absence of concussion or other clinical diagnoses.

(iv) A warning that the device is not a stand-alone diagnostic.

(v) Any instructions technicians must convey to patients regarding the administration of the test and collection of cognitive test data.

Dated: November 30, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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