

* * * * *

R. Gil Kerlikowske,
Commissioner, U.S. Customs and Border
Protection.

Approved: December 1, 2016.

Timothy E. Skud,
Deputy Assistant Secretary of the Treasury.

[FR Doc. 2016-29191 Filed 12-5-16; 8:45 am]

BILLING CODE 9111-14-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 December 6, 2016. The classification was applicable on August 22, 2016.

FOR FURTHER INFORMATION CONTACT: Stacie Gutowski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2656, Silver Spring, MD 20993-0002, 240-402-6032, Stacie.Gutowski@fda.hhs.gov.

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) 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.	<ul style="list-style-type: none"> • Labeling. • 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.

[FR Doc. 2016-29134 Filed 12-5-16; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 5, 91, 92, 93, 200, 247, 574, 576, 578, 880, 882, 883, 884, 886, 891, 905, 960, 966, 982, and 983

[Docket No. FR 5720-C-04]

Violence Against Women Reauthorization Act of 2013: Implementation in HUD Housing Programs; Correction

AGENCY: Office of General Counsel, HUD.

ACTION: Final rule; correction.

SUMMARY: On November 16, 2016, HUD published a final rule implementing in HUD's regulations the requirements of the 2013 reauthorization of the Violence Against Women Act (VAWA). After publication, HUD discovered an incorrect compliance date in the preamble and an incorrect paragraph designation in the regulatory text. The compliance date, with respect to completing an emergency transfer plan and providing emergency transfers, and associated recordkeeping and reporting requirements, was incorrectly listed as May 15, 2017, in the preamble. The regulatory text provided the correct date of June 14, 2017. This document makes the necessary correction to the preamble to reflect the compliance date in the regulatory text of June 14, 2017 and the paragraph designations in the regulatory text.

DATES: This correction is effective December 16, 2016.

FOR FURTHER INFORMATION CONTACT:

With respect to this supplementary document, contact Ariel Pereira, Associate General Counsel for Legislation and Regulations, Department of Housing and Urban Development, 451 7th Street SW., Room 10238, Washington, DC 20410; telephone number 202-708-1793 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800-877-8339.

SUPPLEMENTARY INFORMATION: In the final rule FR Doc. 5720-F-03, beginning

on page 80724 in the **Federal Register** of November 16, 2016, the following corrections are made:

1. In the **DATES** section, on page 80724 in the second column, revise "May 15, 2017" to read "June 14, 2017".

2. In the II.B SUMMARY OF PUBLIC COMMENTS AND HUD RESPONSES section, on page 80790 in the second column, revise "May 15, 2017" to read "June 14, 2017".

§ 578.99 [Corrected]

■ 3. On page 80810, in the second column, in the 24 CFR 578.99 regulatory text, the second set of paragraphs (j)(2)(i) through (iii) is redesignated as (j)(2)(iii)(A) through (C).

Dated: December 1, 2016.

Ariel Pereira,

Associate General Counsel for Legislation and Regulations.

[FR Doc. 2016-29213 Filed 12-5-16; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2016-1042]

Drawbridge Operation Regulation; Inner Harbor Navigation Canal, New Orleans, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulations.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the L & N Railroad/Almonaster Road drawbridge across the Inner Harbor Navigation Canal, mile 2.9 at New Orleans, Orleans Parish, Louisiana. The deviation is necessary to conduct repair and replacement of the lift rail assembly on the south end of the bridge. These repairs are essential for the continued safe operation of the bridge. This deviation allows the bridge to remain closed-to-navigation for ten hours with a scheduled one-hour opening to facilitate passage of vessel traffic.

DATES: This deviation is effective from 7 a.m. through 5 p.m., on December 15, 2016.

ADDRESSES: The docket for this deviation, [USCG-2016-1042] is available at <http://www.regulations.gov>. Type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Giselle MacDonald, Bridge Administration Branch, Coast Guard, telephone (504) 671-2128, email Giselle.T.MacDonald@uscg.mil.

SUPPLEMENTARY INFORMATION: CXS

Transportation, through the Port of New Orleans, requested a temporary deviation from the operating schedule of the L & N Railroad/Almonaster Road drawbridge across the Inner Harbor Navigation Canal, mile 2.9 at New Orleans, Orleans Parish, Louisiana.

The vertical clearance of the L & N Railroad/Almonaster Road bascule bridge is one foot above high water in the closed-to-navigation position and unlimited clearance in the open-to-navigation position. Navigation on the waterway consists of tugs with tows, small ships, fishing vessels, sailing vessels, and other recreational craft. In accordance with 33 CFR 117.5, the draw shall open on signal for the passage of vessels.

This deviation allows the drawbridge to remain in the closed-to-navigation position from 7 a.m. through 11 a.m. and from noon through 5 p.m. on Thursday, December 15, 2016, with the bridge scheduled to open at 11 a.m. through noon for the passage of all waiting vessels.

The bridge will not be able to open for the passage of vessels except during the one-hour scheduled opening. Alternate routes are available via the Chef Menteur Pass and the Rigolets.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: December 1, 2016.

David M. Frank,

Bridge Administrator, Eighth Coast Guard District.

[FR Doc. 2016-29177 Filed 12-5-16; 8:45 am]

BILLING CODE 9110-04-P