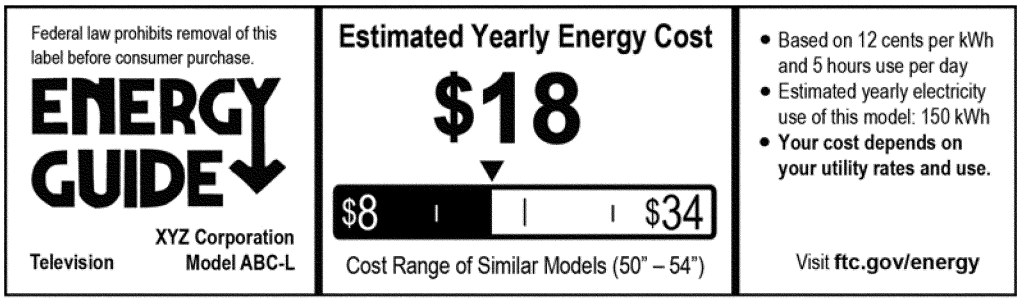

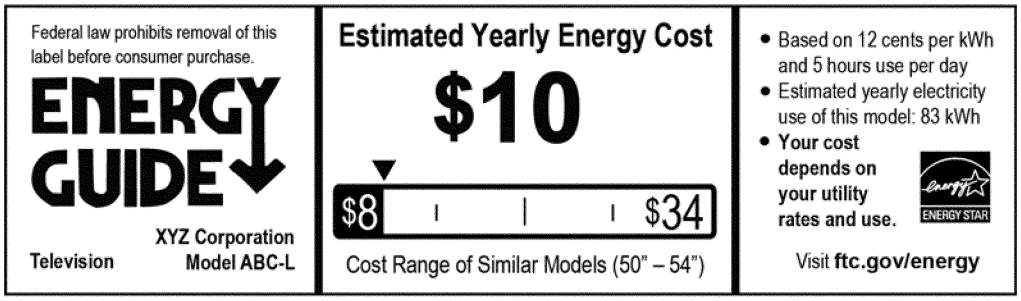

Sample Label 16

Horizontal Television Labels

* * * * *

By direction of the Commission.

Donald S. Clark

Secretary.

[FR Doc. 2015–07070 Filed 3–26–15; 8:45 am]

BILLING CODE 6750–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2015–N–0802]

Medical Devices; Neurological Devices; Classification of the Brain Injury Adjunctive Interpretive Electroencephalograph Assessment Aid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the brain injury adjunctive interpretive electroencephalograph assessment aid 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 brain injury adjunctive interpretive electroencephalograph assessment aid'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 March 27, 2015. The classification was applicable on November 17, 2014.

FOR FURTHER INFORMATION CONTACT: Jay Gupta, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G312, Silver Spring, MD 20993–0002, 301–796–2795, *jay.gupta@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 postamendments 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 will classify the device by written order within 120 days. This classification will be the initial classification of the device.

On August 20, 2014, BrainScope Company, Inc., submitted a request for classification of the BrainScope Ahead 100, Models CV–100 and M–100 under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

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 November 17, 2014, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding § 882.1450.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a brain injury adjunctive interpretive electroencephalograph assessment aid will need to comply with the special controls named in this final order. The device is assigned the generic name brain injury adjunctive interpretive electroencephalograph assessment aid, and it is identified as a prescription device that uses a patient's electroencephalograph (EEG) to provide an interpretation of the structural condition of the patient's brain in the setting of trauma. A brain injury adjunctive interpretive EEG assessment aid is for use as an adjunct to standard clinical practice only as an assessment aid for a medical condition for which there exists other valid methods of diagnosis.

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—BRAIN INJURY ADJUNCTIVE INTERPRETIVE ELECTROENCEPHALOGRAPH ASSESSMENT AID RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measure
Adverse tissue reaction	Biocompatibility. Labeling.
Equipment malfunction leading to injury to user/patient (shock, burn, or mechanical failure).	Electrical safety, thermal, and mechanical testing. Electromagnetic compatibility testing. Labeling.
Delay in treatment or unnecessary treatment due to hardware or software failure.	Performance testing. Hardware and software verification, validation and hazard analysis. Electromagnetic compatibility testing. Technical parameters Labeling.
False result due to incorrect artifact reduction	Software verification and validation. Labeling.
False result due to incorrect placement of electrodes	Clinical performance testing. Labeling.
False result when a brain injury adjunctive interpretive EEG assessment aid impacts the clinical decision.	Clinical performance testing. Device design characteristics. Labeling.
Use error	Clinical performance testing. Labeling.

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

- The technical parameters of the device, hardware and software, must be fully characterized and include the following information:
  - Hardware specifications must be provided. Appropriate verification, validation, and hazard analysis must be performed.
  - Software, including any proprietary algorithm(s) used by the device to arrive at its interpretation of the patient's condition, must be described in detail in the software requirements specification (SRS) and software design specification (SDS). Appropriate software verification, validation, and hazard analysis must be performed.
- The device parts that contact the patient must be demonstrated to be biocompatible.
- The device must be designed and tested for electrical safety, electromagnetic compatibility (EMC), thermal, and mechanical safety.
- Clinical performance testing must demonstrate the accuracy, precision-repeatability and reproducibility, of determining the EEG-based

interpretation, including any specified equivocal zones (cut-offs).

- Clinical performance testing must demonstrate the ability of the device to function as an assessment aid for the medical condition for which the device is indicated. Performance measures must demonstrate device performance characteristics per the intended use in the intended use environment. Performance measurements must include sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) with respect to the study prevalence per the device intended use.
- The device design must include safeguards to ensure appropriate clinical interpretation of the device output (*e.g.,* use in appropriate patient population, or for appropriate clinical decision).
- The labeling and training information must include:
  - A warning that the device is not to be used as a stand-alone diagnostic.
  - A detailed summary of the clinical performance testing, including any adverse events and complications.
  - The intended use population and the intended use environment.
  - Any instructions technicians should convey to patients regarding the collection of EEG data.
  - Information allowing clinicians to gauge clinical risk associated with integrating the EEG interpretive assessment aid into their diagnostic pathway.
  - Information allowing clinicians to understand how to integrate the device output into their diagnostic pathway when the device is unable to provide a classification or final result.

Brain injury adjunctive interpretive electroencephalograph assessment aid devices are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device; see 21 CFR 801.109 (*Prescription devices*)). Prescription-use restrictions are a type of general controls as defined in section 513(a)(1)(A)(i) of the FD&C Act.

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. 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 brain injury adjunctive interpretive electroencephalograph assessment aid they intend to market.

II. 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 21 CFR 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.

IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov.*

1. [DEN140025]: De Novo Request per 513(f)(2) from BrainScope Company, Inc., dated August 20, 2014.

List of Subjects in 21 CFR Part 882

Medical devices, Neurological 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 21 CFR part 882 continues to read as follows:

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

■ 2. Add § 882.1450 to subpart B to read as follows:

§ 882.1450 Brain injury adjunctive interpretive electroencephalograph assessment aid.

(a) *Identification.* A brain injury adjunctive interpretive electroencephalograph assessment aid is a prescription device that uses a patient's electroencephalograph (EEG) to provide an interpretation of the structural condition of the patient's brain in the setting of trauma. A brain injury adjunctive interpretive EEG assessment aid is for use as an adjunct to standard clinical practice only as an assessment aid for a medical condition for which there exists other valid methods of diagnosis.

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

(1) The technical parameters of the device, hardware and software, must be fully characterized and include the following information:

(i) Hardware specifications must be provided. Appropriate verification, validation, and hazard analysis must be performed.

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

(2) The device parts that contact the patient must be demonstrated to be biocompatible.

(3) The device must be designed and tested for electrical safety, electromagnetic compatibility (EMC), thermal, and mechanical safety.

(4) Clinical performance testing must demonstrate the accuracy, precision-repeatability and reproducibility, of determining the EEG-based interpretation, including any specified equivocal zones (cutoffs).

(5) Clinical performance testing must demonstrate the ability of the device to function as an assessment aid for the medical condition for which the device is indicated. Performance measures must demonstrate device performance characteristics per the intended use in the intended use environment. Performance measurements must include sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) with respect to the study prevalence per the device intended use.

(6) The device design must include safeguards to ensure appropriate clinical interpretation of the device output (*e.g.,*

use in appropriate patient population, or for appropriate clinical decision).

(7) The labeling and training information must include:

(i) A warning that the device is not to be used as a stand-alone diagnostic.

(ii) A detailed summary of the clinical performance testing, including any adverse events and complications.

(iii) The intended use population and the intended use environment.

(iv) Any instructions technicians should convey to patients regarding the collection of EEG data.

(v) Information allowing clinicians to gauge clinical risk associated with integrating the EEG interpretive assessment aid into their diagnostic pathway.

(vi) Information allowing clinicians to understand how to integrate the device output into their diagnostic pathway when the device is unable to provide a classification or final result.

Dated: March 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–07010 Filed 3–26–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 66

[Docket ID: DOD–2011–OS–0099]

RIN 0790–AI78

Qualification Standards for Enlistment, Appointment, and Induction

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: Interim final rule.

SUMMARY: This rule updates policies and responsibilities for basic entrance qualification standards for enlistment, appointment, and induction into the Armed Forces and delegates the authority to specify certain standards to the Secretaries of the Military Departments. It establishes the age, aptitude, character/conduct, citizenship, dependents, education, medical, physical fitness, and other disqualifying conditions that are causes for rejection from military service. Other standards may be prescribed in the event of mobilization or national emergency. This rule sets standards designed to ensure that individuals under consideration for enlistment, appointment, and/or induction are able to perform military duties successfully, and to select those who are the most trainable and adaptable to Service life.

DATES: *Effective Date:* This rule is effective March 27, 2015. Comments must be received by May 26, 2015.

ADDRESSES: You may submit comments, identified by docket number and or Regulatory Information Number (RIN) and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, 2nd Floor, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number or RIN for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Dennis J. Drogo, (703) 697–9268.

SUPPLEMENTARY INFORMATION:

Executive Summary

I. Purpose of This Regulatory Action

This rule updates policies and responsibilities for basic entrance qualification standards for enlistment, appointment, and induction into the Armed Forces and delegates the authority to specify certain standards to the Secretaries of the Military Departments.

II. Summary of the Major Provisions of This Regulatory Action

(a) Establishes age, aptitude, character/conduct, citizenship, dependents, education, medical, physical fitness, and other disqualifying conditions that are causes for rejection from military service. Other standards may be prescribed in the event of mobilization or national emergency.

(b) Sets standards designed to ensure that individuals under consideration for enlistment, appointment, and/or induction are able to perform military duties successfully and to select those who are the most trainable and adaptable to Service life.

(c) Removes provisions related to homosexual conduct.

III. Costs and Benefits of This Regulatory Action

The benefit of publishing this interim final rule is that it establishes standards to ensure that those who are enlisted, appointed, or inducted are the best qualified to complete their prescribed training and the best able to adapt to the military life. Failure to maintain these standards would result in a high attrition of personnel and would significantly increase training costs. The success of today's All-volunteer military is dependent on this policy.

Justification for Interim Final Rule

This rule is being published as an interim final rule to provide required updates in DoD policy and procedures that impact the public. It has been almost 10 years since these policies and procedures have been updated. Some policy changes and court decisions have a great impact on the eligibility of potential applicants entry into the military. All language addressing homosexual conduct has been removed in accordance with the December 22, 2010, repeal of the Don't Ask Don't Tell policy, which opened military service to homosexuals, and the subsequent *United States* vs. *Windsor* decision (570 U.S. 12, 133 S. Ct 2675 (2013)) which found section 3 of the Defense of Marriage Act (DOMA) unconstitutional. By removing all references to homosexuality, otherwise qualified applicants are now free to apply and enroll in a military academy without prejudice or fear of reprisal. This interim rule is required immediately to remove any legal and policy restrictions which would prevent a potential applicant from entry into a military based solely on their sexual orientation.

It is important for DoD to have current and up-to-date enlistment, appointment, and induction standards, which are essential in defining the measures necessary to evaluate and qualify civilians for military service. A critical component of this update is the clarification of one of the underlying purposes of the enlistment, appointment, and induction standards which is to minimize entrance of persons who are likely to become disciplinary cases, security risks, or who are likely to disrupt good order, morale, and discipline. The Military Services are responsible for the defense of the Nation and should not be viewed as a source of rehabilitation for those who have not subscribed to the legal and moral standards of society at-large. The necessity of publishing these current standards, as an interim final rule, is vital to the DoD meeting its mission to man the All Volunteer Force with qualified citizens.