



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 5, 2015

Cerebral Assessment Systems, Inc.
Charles J. Duffy, MD, PhD, Founder and CEO
2850 Clover Street
Pittsford, NY 14534

Re: DEN130033
Cognivue
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 882.1470
Regulation Name: Computerized Cognitive Assessment Aid
Regulatory Classification: Class II
Product Code: PKQ
Dated: June 24, 2013
Received: June 26, 2013

Dear Dr. Duffy:

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 Cognivue, a prescription device under 21 CFR Part 801.109 that is indicated for use *as an adjunctive tool for evaluating perceptual and memory function in individuals aged 55-95 years old*. FDA concludes that this device should be classified into class II. This order, therefore, classifies Cognivue, and substantially equivalent devices of this generic type, into class II under the generic name, Computerized Cognitive Assessment Aid.

FDA identifies this generic type of device as:

Computerized Cognitive Assessment Aid: The Computerized Cognitive Assessment Aid is a prescription device that uses an individual's score(s) on a battery of cognitive tasks to provide an interpretation of the current level of cognitive function. The Computerized Cognitive Assessment Aid is used only as an assessment aid to determine level of cognitive functioning for which there exists other valid methods of cognitive assessment and does not identify the presence or absence of clinical diagnoses. The Computerized Cognitive Assessment Aid is not intended as a stand-alone or adjunctive diagnostic device.

Section 513(f)(2) of 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 June 24, 2013, FDA received your *de novo* requesting classification of Cognivue into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify Cognivue 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 for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that Cognivue, indicated for use *as an adjunctive tool for evaluating perceptual and memory function in individuals aged 55-95 years old*, can be classified in class II with the establishment of special controls for class II. 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
Equipment malfunction leading to subject injury (shock, burn, or mechanical failure)	Electrical safety testing Labeling
User discomfort (e.g., visual fatigue, stimulus-induced nausea)	Labeling
Incorrect result, inclusive of: <ul style="list-style-type: none"> • False positive – cognitive impairment when, in fact, none is present • False negative – cognitive impairment when, in fact, cognitive impairment is present 	Hardware and Software verification, validation and hazard analysis Labeling

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

1. The technical parameters of the device’s hardware and software must be fully characterized and be accompanied by appropriate non-clinical testing:
 - a. Hardware specifications must be provided. Appropriate verification, validation and hazard analysis must be performed.
 - b. 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). Appropriate software verification, validation, and hazard analysis must be performed.
2. The device must be designed and tested for electrical safety.

3. The labeling must include:
 - a. A summary of any testing conducted to demonstrate how the device functions as an interpretation of the current level of cognitive function. The summary of testing must include the following, if available: any expected or observed adverse events and complications; any performance measurements including sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) per the device intended use; a description of the repeatability of measurements; a description of how the cut-off values for categorization of measurements were determined; and a description of the construct validity of the device.
 - b. A warning that the device does not identify the presence or absence of clinical diagnoses.
 - c. A warning that the device is not a stand-alone diagnostic.
 - d. The intended use population and the intended use environment.
 - e. Any instructions technicians must convey to patients regarding the administration of the test and collection of cognitive test data.

In addition, this is a prescription device 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 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 device complies 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 device 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 Peter G. Como, Ph.D. at 301-796-6919.

Sincerely yours,

Jonette R. Foy -S

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