DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 18, 2015

Wicab Inc.
% Steven B. Datlof, MD, JD
Partner
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, PA 19103

Re: DEN130039
BrainPort V100
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 886.5905
Regulation Name: Oral Electronic Vision Aid
Regulatory Classification: Class II
Product Code: PIC
Dated: August 7, 2013
Received: August 7, 2013

Dear Dr. Datlof:

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 BrainPort V100, a prescription device under 21 CFR Part 801.109 that is indicated for use as *an oral electronic vision aid that provides electro-tactile stimulation to aid profoundly blind patients in orientation, mobility, and object recognition as an adjunctive device to other assistive methods such as the white cane or a guide dog.* FDA concludes that this device should be classified into class II. This order, therefore, classifies the BrainPort V100 and substantially equivalent devices of this generic type, into class II under the generic name, Oral electronic vision aid.

FDA identifies this generic type of device as:

> **Oral electronic vision aid.** An oral electronic vision aid is a battery-powered prescription device that contains an electrode stimulation array to generate electro-tactile stimulation patterns that are derived from digital object images captured by a camera. It is intended to aid profoundly blind patients in orientation, mobility, and object recognition as an adjunctive device to other assistive methods such as the white cane or a guide dog.

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 7, 2013, FDA received your *de novo* requesting classification of the BrainPort V100 into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Brainport V100 into class 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 the BrainPort V100, intended for use as an electronic assistive device for the profoundly blind to aid in orientation, mobility and object recognition, can be classified in 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 Method**
Irritation, Discomfort or Adverse Events Involving the Mouth, Tongue, or Gums	Clinical Testing Labeling
Adverse Tissue Reaction	Biocompatibility Testing Labeling
Unit (Hardware) Malfunction, Functional Reliability	Non-Clinical Performance Testing Clinical Testing Labeling
Software Malfunction	Software Verification, Validation, and Hazard Analysis
Use Error	Clinical Testing Healthcare Professional Training Patient Training Labeling
Interference with Other Devices	Electromagnetic Compatibility (EMC) and Electromagnetic Interference (EMI) Testing Wireless Coexistence Testing Labeling
Electrical Shock	Electrical Safety Testing Labeling

In combination with the general controls of the FD&C Act, the oral electronic vision aid is subject to the following special controls:

1. Clinical performance testing must demonstrate an acceptable adverse event profile, including adverse events involving the mouth, tongue, and gums and demonstrate the effect of the stimulation to provide clinically meaningful outcomes. The clinical performance testing must also investigate the anticipated conditions of use, including potential use-error, intended environment of use, and duration of use.
2. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including simulated moisture ingress, device durability, and battery reliability.
3. Software verification, validation and hazard analysis must be performed.
4. Analysis/testing must validate electromagnetic compatibility (EMC).
5. Analysis/testing must validate electrical safety.
6. Analysis/testing must assess and validate wireless coexistence concerns.
   Any elements of the device that contact the patient must be demonstrated to be biocompatible.
7. Training must include elements to ensure that the healthcare provider and user can identify the safe environments for device use, use all safety features of the device, and operate the device in the intended environment of use.
8. Labeling for the trainer and user must include a summary of the clinical testing including, adverse events encountered under use conditions, summary of study outcomes and endpoints; and information pertinent to use of the device including the conditions under which the device was studied (e.g., level of supervision or assistance, and environment of use).

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 oral electronic vision 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 Dexiu Shi, Ph.D., at 301-796-6470.

Sincerely yours,

Jonette R. Foy -S

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