



Food and Drug Administration
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December 24, 2015

Wicab, Inc.
c/o Steven B. Datlof, M.D., J.D.
Partner
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, PA 19103

Re: K152851

Trade/Device Name: BrainPort V100
Regulation Number: 21 CFR 886.5905
Regulation Name: Oral electronic vision aid
Regulatory Class: Class II
Product Code: PIC
Dated: September 29, 2015
Received: September 29, 2015

Dear Dr. Datlof:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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 Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number : K152851

Device Name

BrainPort V100

Indications for Use *(Describe)*

The BrainPort V100 is 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.

Type of Use *(Select one or both, as applicable)*

Prescription Use (Part 21 CFR 801 Subpart D)
Subpart C)

Over-The-Counter Use (21 CFR 801

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY (K152851)

Wicab Inc.'s BrainPort V100

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Wicab, Inc.
8313 Greenway Blvd.
Suite 100
Middleton, WI 53562
Phone: 608-829-4500
Facsimile: 608-829-4501
Contact Person: Robert Beckman, President and CEO

Date Prepared: December 21, 2015

Name of Device and Name/Address of Sponsor

BrainPort V100
Wicab, Inc.
8313 Greenway Blvd., Suite 100
Middleton, WI 53562

Common or Usual Name/Classification

Oral Electronic Vision Aid
21 CFR 886.5905, product code PIC, class II

Predicate/Reference Devices

Predicate Device: Wicab, Inc. BrainPort V100 (DEN130039)

Intended Use / Indications for Use

The BrainPort V100 is 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.

Technological Characteristics

The BrainPort V100 has the same intended use and indications for use as previously granted for the BrainPort V100 (DEN130039). In addition, the device has very similar technological characteristics and operating principles as the predicate. The BrainPort V100 design and components are the same as the previously granted BrainPort V100; the device continues to consist of the headset, controller (handset), intra-oral device (IOD), and battery charger. The

camera unit in the headset captures the viewed scene as a digital image and forwards that image to the controller for processing. The IOD presents stimulation patterns representative of the camera image to the user's tongue. Same as in DEN130039, the BrainPort V100 is a fully wearable, battery operated device with no physical connections to external equipment during normal operation. The device includes a means for a sighted individual (e.g., instructor) to remotely view the camera and IOD images to assist in training through its vRemote software program.

Similarities and differences from the predicate device are described below:

Modified IOD may be used by multiple users in the training period:

Similarities: No change in the IOD component. No change in how the user uses the device during and after the training period. Testing verified that there is no change in the electrode function of the modified device.

Differences: Validated cleaning and disinfection procedures, described below. If multiple users use the IOD during the training period, the BrainPort V100 device must be returned to Wicab for high level disinfection between users according to instructions provided in the device manual.

Minor software change:

Similarities: No change in how the device is used. The modified device functions in the same manner as the predicate device. Verification and validation testing ensured that the updated software performs as intended.

Differences: Minor update changes the location of the audio .wav files. No other hardware or software changes were made.

Therefore, the technological characteristics of the device remain very similar to the device previously de novo granted in DEN130039.

Performance Data

Cleaning/Disinfection Validation: Cleaning and disinfection validation testing for the IOD component of the BrainPort V100 was conducted by an independent laboratory in accordance with guidelines outlined in AAMI TIR12:2010, AAMI TIR30:2011, ISO 17664:2004, ANSI/AAMI ST81:2004(R)2010, and ANSI/AAMI ST58:2013. All results were passing, validating the cleaning and disinfection procedures. Results from performance testing also verified that the cleaning and disinfection procedures do not reduce electrode functionality.

Electrical Safety/Electromagnetic Compatibility: Electrical Safety and Electromagnetic Compatibility testing were conducted in accordance with the applicable standards IEC 60601-1, IEC 60601-1-2, and IEC 60601-1-11. Results were passing. There have been no changes in electronic hardware/technology compared to the predicate device.

Biocompatibility: The biocompatibility of the BrainPort V100 was established, and further supports the low risk of the BrainPort V100. There have been no changes to the device materials compared to the predicate.

Software: Software verification and validation testing was conducted, and results demonstrated that the software was appropriate for release.

Substantial Equivalence

The BrainPort V100 and the predicate device have the same intended use and indications for use. The BrainPort V100 system presents very similar technological characteristics and principles of operation as its predicate device. The minor difference in the software does not present any new types of safety or effectiveness questions since the BrainPort V100 performance and energy outputs remain the same. In addition, the cleaning and disinfection test reports validate the procedures for multiple patient use. Thus, the BrainPort V100 is substantially equivalent to its predicate (DEN130039).

Conclusions

The BrainPort V100 is substantially equivalent to its predicate device. Results from the cleaning and disinfection tests support multiple patient use of the BrainPort V100 during the training period. Furthermore, results from prior testing also demonstrate that the BrainPort V100 functions as intended. Therefore, Wicab believes the provided information is sufficient to demonstrate the substantial equivalence of the BrainPort V100 to its predicate device in support of clearance.