DE NOVO CLASSIFICATION REQUEST FOR
BRAINPORT V100

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 886.5905

CLASSIFICATION: CLASS II

PRODUCT CODE: PIC

BACKGROUND

DEVICE NAME: BRAINPORT V100

SUBMISSION NUMBER DEN130039

DATE OF DE NOVO: August 7, 2013

CONTACT: Wicab Inc.
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Middleton, WI 53562
608-829-4500

REQUESTER'S RECOMMENDED CLASSIFICATION: CLASS II

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.

LIMITATIONS

BrainPort V100 is indicated for prescription use only.

Candidates for the device should be profoundly blind.

Contraindications:

- Any neurological condition that causes impaired sensitivity to the tongue or loss of consciousness

Warnings:

- Limited data are available on the long-term effects of electrical stimulation of the tongue. Long-term effects (beyond one year) have not been evaluated in clinical trials.
- The BrainPort V100 should be not used in patients experiencing numbness or lack of feeling of the tongue, or in patients with a history of injury to the tongue resulting in impaired sensation or use of the tongue.
- The BrainPort V100 should only be used after the user has completed training. Do not give the device to untrained individuals for use.
- Limited data are available on stimulation sensitivity for individuals with oral conditions such as oral ulcerations, herpes simplex, oral thrush, and geographic tongue. If use of the device causes discomfort, discontinue use.
- The BrainPort V100 has not been thoroughly evaluated in the presence of dental implants. The safety of dental implants in BrainPort users is unknown. The use of this device potentially may cause heating of dental implants; chronic use of this device potentially may result in loosening and failure of dental implants.
- The BrainPort V100 is not used to diagnose or treat the underlying condition that leads to the user's visual impairment.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The BrainPort V100 is an electronic assistive aid that translates images of objects captured by a digital camera into electro-tactile signals that are presented to the user's tongue. With training, users are able to use the electrotactile signals to perceive shape, size, location and motion of objects. The BrainPort V100 is intended to augment, rather than replace, other assistive technology such as the white cane or guide dog. The BrainPort V100 is not used to diagnose or treat the underlying condition that leads to the user's visual impairment. The BrainPort V100 is intended for prescription use only and for single patient use

The BrainPort V100 consists of three components: the headset, the controller (also known as the handset), and the battery charger as depicted in **Figure 1**. The headset is typically worn on the user's head and provides the image input and output functions of the device. The controller is generally handheld and provides the processing and power functions of the device. The battery charger is a commercial off-the-shelf unit used to charge the removable battery.

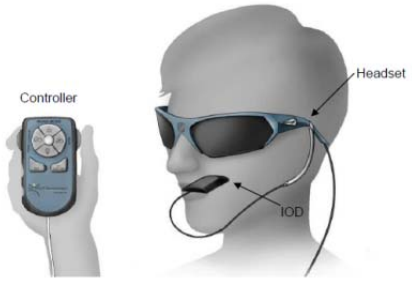


Figure 1: Artist Rendition of BrainPort V100 components: Controller and Headset

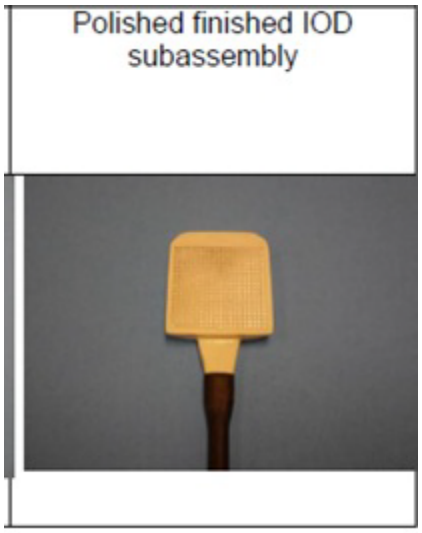
Headset

A digital video camera is mounted on a pair of sunglasses at the nose bridge. The field of view of the camera is user-controlled and varies from narrow to wide angle views. There are two cables permanently attached to the left ear piece: the IOD assembly and the headset cable.

Intra Oral Device (IOD)

The IOD (tongue electrode array) contains electrodes that act as "pixels" for the tongue. The flat side with the electrodes should be in contact with the front top surface of the tongue. The user should close their lips around the thin stem, maximizing tongue contact with the electrodes. The electrodes provide stimulation to the tongue based on information received from the camera. The electrodes provide electro-tactile information that varies based on the size, location and relative luminance of objects within a visual scene. There is one cable exiting the thin stem of the IOD that is permanently attached to the ear piece of the headset. **Figure 2** below presents the IOD sub-assembly of the BrainPort V100.

Figure 2 - IOD Subassembly of the BrainPort V100



Controller

The Controller contains the battery as well as the user control features for the BrainPort V100. An antenna provides wireless connection capabilities. The Controller is generally handheld. A belt clip is provided for hands free operation.

Battery & Battery Charger

Rechargeable Lithium-Polymer batteries and a battery charger with factory instructions are included with each BrainPort V100. All batteries included with the system should be fully charged at 3.7VDC prior to initial use.

The general specifications for the BrainPort V100 are listed in Table 1:

Table 1- Relevant Product Specifications

Physical	Length 13.3 cm width 5.6 cm height 3.5 cm (excluding belt clip) weight <175 g (including battery) Cable length to headset 106 cm
Power	Internally powered by a lithium polymer rechargeable battery (3.7V, 2260mAh, 8.4Wh)
Output Waveforms	Monophasic Capacitive coupling
Pulse Frequency	200 Hz
Pulse Width	25 µs
Surface Area	0.46 mm² (per electrode)
Voltage	0 to 1.414 V rms (per electrode) 0 to 14.14 V rms (device)
Current	0 to 0.518 mA rms (per electrode) 0 to 20.7 mA rms (device)
Energy/pulse	10.35µJ

TRAINING

The training philosophy is to facilitate the user's self-discovery of linking BrainPort V100 derived perception with the user's lifetime of multi-sensory experiences. The trainer provides activities where the user explores a situation in his typical manner (i.e., by reaching, touching, listening, etc.). The user then observes how that same situation is represented by the BrainPort V100.

To ensure proper use of the device, BrainPort V100 professionals and users are required to undergo training. Potential trainers of users of the BrainPort V100 should have relevant experience, such as experience working with the blind or visually impaired as well as professional credentials, such as certification as a Certified Low Vision Specialists (CLVS), Certified Orientation and Mobility Specialist (COMS) or Teachers of the Visually Impaired (TVI). All potential trainers will be further trained by Wicab according to Wicab procedures and only those who have successfully completed the training will be considered qualified to train users of the BrainPort V100. As part of the training program, a specialist from Wicab provides a demonstration to the trainer of typical training session(s), covering all tasks that are typically completed over several days of end user training. First, the specialist operates the BrainPort V100 and focuses the trainer on the vRemote output to demonstrate how to monitor a user's performance and provide appropriate feedback and instruction to the user.

Second, the specialist supervises the trainer performing training with a new user (or blind-folded simulation) as outlined in the training procedures. During this hands-on phase, the specialist interjects and provides suggestions for improved training or user performance. This exercise is to ensure that the trainer can provide suitable training with the BrainPort V100.

Lastly, a Trainer and Patient Manual (printed and auditory format) of the BrainPort V100 is provided. The user profile is summarized in Table 2:

Table 2 - User Profile

User	For use by individuals who are profoundly blind.
Education	Completed traditional blindness rehabilitation: white cane, and/or guide dog, and rehabilitation in activities of daily living
Knowledge	Minimum: ability to understand verbal training instructions Reading and comprehension at 10th grade level
Experience	All users must participate in a minimum of 10 hours of supervised training per Wicab's training protocol prior to unsupervised use of the device
Permissible Impairments	Diagnosis of no light perception or light perception Blindness may be acquired or congenital Absence of oral sensory impairments

vRemote Feature

There are two ways to use the BrainPort V100: in standalone mode or in Wi-Fi mode to connect to Wicab's proprietary application software vRemote (Wicab Reference Number: SW- 000014). The software package (vRemote) receives data from a BrainPort V100 device and displays it on a computer. The optional Wi-Fi communications capability provides one way only transfer from the V100 to the PC screen. It provides information to the trainer about stimulation intensity, zoom, exposure, tilt, and inversion settings of the BrainPort V100 device. There is no patient information contained in Wi-Fi communications. The user will be advised that if the vRemote is used by the user's companion, it should not be used by the companion to provide any instructions to the user, but is simply for viewing.

The hardware and software of the BrainPort V100 device were designed and developed to ensure accurate and reliable wireless transmission of device data. The personal computer used to run the vRemote software must have an operating system of Windows XP or higher (.NET 4.0 or higher), and must be able to establish an 'ad-hoc' Wi-Fi connection (minimum 802.11 a/b) with the BrainPort V100 device.

SUMMARY OF NONCLINICAL/BENCH STUDIES

A. BIOCOMPATIBILITY/MATERIALS

The patient-contacting components of the BrainPort V100 are the IOD and cable & headset sleeve, which are identified in Table 3.

Table 3 – Materials of Patient Contact

Component	Material
Intra-oral Device (IOD) (oral contact)	b(4)
Cable & Headset Sleeve (skin contact)	b(4)

The applicant conducted a biological risk assessment and applicable test on these materials based on ISO10993-1 (Biological Evaluation of Medical Devices). Additionally, the patient contacting materials in BrainPort V100 are well characterized in oral electro- stimulating application and an assessment was deemed adequate to ensure sufficient biocompatibility.

B. SHELF LIFE/STERILITY

The BrainPort V100 is a non-sterile, single user reusable device.

There is no specified shelf life for the device, which is acceptable based upon the nature of the device components. However, because the IOD does come in contact with the patient's lips and tongue, and is further intended for re-use, the Instructions for Use include cleaning. It recommended to clean the IOD once per week using 70% isopropyl alcohol (rubbing alcohol), which has been tested and shown to be compatible with the materials used in the IOD. To avoid damage to the IOD, it should not be exposed to any bleach agents.

C. ELECTRICAL SAFETY, ELECTROMAGNETIC COMPATIBILITY (EMC) AND GENERAL ELECTRICAL TESTING

1. **ELECTRICAL SAFETY**

   The device was tested per IEC 60601-1: 2005 (3rd edition) and IEC 60601-1-2: 2007. The device is in conformance with the standards and passed applicable sub-clauses.

2. **ELECTROMAGNETIC COMPATIBILITY (EMC)**

   Testing was performed to address EMC concerns for this device, which is intended to be used in hospital and home-use environments. The device was tested and evaluated per the IEC 60601-1-2:2007 criteria and the device was tested at higher levels for home-use: specifically electrostatic discharge (ESD) at +/- 8 kV contact discharge, +/-15 kV air discharge, power frequency magnetic field at 30 A/m, Conducted RF Immunity: 6 V r.m.s. and radiated RF at 10 V/m. All results demonstrated acceptable performance.

   EMC labeling, as necessary to claim compliance with IEC 60601-1-2:2007, has been included in the Trainer and User Manuals. This includes tests at higher test levels than the recommended hospital environment.

3. **BATTERY TESTING**

   Battery testing was conducted to show the device is sufficiently able to detect when the battery capacity is low. In a low battery condition, the device may shutdown automatically leaving the patient without feedback. Thus, when the battery level decreases to the designated low level, the device will repeatedly announce “low battery.” This announcement acts as a reminder that a replacement battery should be inserted in order to continue using the device.

   The battery supplied with the BrainPort V100 is a rechargeable Lithium-Polymer battery. When fully charged, the battery provides approximately three hours of use and is expected to last through more than 500 charge cycles.

D. MAGNETIC RESONANCE (MR) COMPATIBILITY

The BrainPort V100 has not been tested for MR compatibility. Therefore, it is not appropriate for this device to be in or near forces encountered in MR imaging suites. Accordingly, the following has been included as part of the labeling:

MR Unsafe. The BrainPort V100 has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating migration, or image artifact in the MR environment. The safety of BrainPort V100 in the MR environment is unknown. The BrainPort V100 should be removed before entering an MR scan room or having an MR scan. Scanning patient who has this device could result in patient injury.

E. SOFTWARE

The BrainPort V100 acquires data from a digital camera and transforms the data to a 400 byte array (an IOD image). Each byte in the IOD image corresponds to an electrode on the IOD. Each value in the array is used to set to a voltage level related to the luminance data in the corresponding camera image: a dark region in the image will result in a low value and a bright region will result in a higher value. Using a progressive scanning technique, the IOD image is presented to electrodes.

Cyber and Information Security Risks

- No patient identifiable information is requested or stored, nor is there a means for the user to enter any such information on the V100 or vRemote (application on PC).
- There is a data exchange between the V100 and vRemote to establish an 'ad hoc' connection between the devices and for the V100 to send status information (including camera and IOD images) to vRemote.
- The data exchange is unencrypted.

Software Verification and Validation

Per the FDA software guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (issued May 11, 2005), the software is considered as a moderate level-of-concern. Among other information, the software documentation included information relating to hazards, software requirements, software development, traceability and potential unresolved anomalies.

F. PERFORMANCE TESTING – BENCH

1. **MOISTURE INGRESS TESTING**

Testing was conducted to characterize the Internal Moisture Penetration of the device. b(4) [redacted] It should be noted that the duration of this test exceeded the observed device usage life of even the most active users by a safety factor of nearly 10. For this test, there were 30 active days of ~23hr of testing per day (690 hrs.). The most active users from the sponsor's clinical study on average had a usage of 530 min per month; 106 hours per

year. Also, 690 hr / 106hr = 6.5 years of use simulated which is more than three times the proposed device service life of 2 years.
Since continuous immersion in a saliva-like environment showed very limited moisture ingress and no penetration to the electronic component area, the opportunity for dendrite growth is limited. In addition, the entire IOD is encapsulated in epoxy, including the electrical components that comprise the active circuitry. However, if there was a short within the IOD electrical components for any reason, including dendrite growth, there would be no anticipated impact on the basic safety of the device.

The BrainPort V100 is classified as IP20. The controller and headset must be kept dry. The device is protected against solid foreign objects over 12 mm. The IOD assembly is IPX4 rated (protection against splashing water).

2. **IOD Durability Test**
Testing was performed to determine the IOD durability. IOD with b(4) . The IOD electrodes were continuously stimulated for 8 days (equivalent to simulating 38 months of normal use). No tarnishing or pitting was observed under visual inspection or 120x optical magnification on any of the electrodes.

Summary of Clinical Information
The applicant conducted a one-year clinical study to demonstrate the safety and effectiveness of the BrainPort V100 device in assisting blind and visually impaired individuals in object recognition and orientation and mobility activities. This study was augmented by additional adverse event data collected outside the United States.

Study Design
The BrainPort V100 device was evaluated in a single arm, open label clinical study of 75 enrolled blind/profoundly blind subjects (visual acuity of light perception or worse) at 7 sites in the U.S. and Canada. Subjects underwent 2-3 days (10 hours) of training followed by in-home use over the span of 12 months.

The duration of each subject's participation was intended to be approximately 12 months. Total study duration was targeted to be approximately 18 months, or a sufficient time to enroll and evaluate 75 subjects with 12 months of device use.

The primary safety objective was to demonstrate an acceptable rate (< 10%) of clinically significant device-related adverse events, which required an observed event-free rate of approximately 97%. In addition, all adverse events were collected and summarized according to seriousness, event type, relationship to device and study procedures as determined by the investigator, severity, action taken, outcome, and whether the event lead to subject withdrawal from study participation.

The applicant conducted the following study assessments:

1. *Object Recognition test*: Four objects were placed in a row on a table draped in black cloth. Subjects were asked to reach out and touch the object requested by the test administrator, without touching any other object. This was repeated for 20 trials. The objects were: softball, coffee mug, plastic banana and a highlighter marker.

2. *Mobility Test:* Four signs were placed in a 15 foot (4.57 meter) hallway. Subjects were asked to find and ambulate to one requested target sign, indicating their response by touching the found sign or within 5 inches (12.7 centimeters) around the perimeter of the designated sign. Signs included: Men's Room, Women's Room, Stairs and Danger.

3. *Oral Health Exam:* Study participants were required to undergo quarterly follow-up evaluations during the year of participation, visiting the study site to receive an oral health exam and to complete assessments of threshold intensity and effectiveness.

4. *Minimum Threshold Test:* A minimum perception threshold on the tongue was recorded using the BrainPort V100 device to assess changes in threshold sensitivity over time. A 4x4 square (16 electrodes) was presented to the user across three trials. Users were instructed to increase intensity to a point where they first feel the stimulation level and the intensity level output will be recorded. Three trials were completed and recorded.

5. *Adverse Event Reports:* All user-initiated adverse event reports, monthly telephone query adverse event reports and adverse event reports resulting from the oral exam were collected.

Study Results

A total of 75 subjects were enrolled, with 74 completing the required device training (Training Phase) prior to entering the "At-Home" Phase. A total of 18 study participants either withdrew consent, or were withdrawn from participation by the principal investigator, prior to completion of the study. The results are provided for both the intent to treat (ITT) and the 'completer' cohorts below.

An internal-control device log was available that was generated by the device. Despite the lower usage reported by subjects in the home logs (i.e., the home training log reported by the subjects), the majority of study subjects achieved or exceeded the minimum device usage target at each quarter and over the 12 month study period based on the device log of the BrainPort V100 usage.

Safety Evaluation: For the primary safety endpoint, the success rate is 100% (57/57) based on the completers and its one-sided 97.5% confidence interval is 93.7%, and therefore the study met the primary safety endpoint.

Adverse Events: The majority of the subjects who reported any adverse events did not require any action and device use continued unchanged. Of the subjects who reported adverse events, 18 subjects had decreased device use or discontinued device use (mostly temporarily), with only two of these subjects reporting events that were considered possibly or probably related to the device. Forty-seven (47) subjects had a total of 137 adverse events during the 12 month investigation. Of these 137 adverse events, 121 were non-serious events. Twenty-eight (28) of these 121 non-serious events were "device-related" and five (5) of those 28 events were "definitely device-related" and constituted changes in taste which were not persistent.

In addition, supplemental safety data (e.g., adverse events) were provided for Wicab's Balance device, which uses the same IOD unit as the one used in the BrainPort V100 device. Of the 148 users from which data were collected, there were no reports of serious device-related adverse events. Three subjects reported non-serious adverse events considered possibly or probably device-related that led to withdrawal or treatment/medical intervention. In addition, Wicab's Balance device has also been used by 617 users outside of the U.S., including consumers and subjects from additional studies that occurred prior to the safety evaluation for the BrainPort V100.

Effectiveness Evaluation: The primary effectiveness endpoint was considered to be met if subjects performed at a rate of 50% or better on the object recognition test. The results showed a success rate was 92.2% (52/57) and its one-sided 97.5% confidence interval was 81.7% for the complete cohort, and therefore the study met the primary effectiveness endpoint. In the worst-case analysis for the ITT cohort, the proportion of responder subjects was 69.3% (52/75) and the lower limit of the one-sided 97.5% confidence interval was 57.6%, which exceeds the performance goal of 50%.

In addition, the training program utilized and validated for this study sufficiently addresses the usability of the device for its intended population. It addressed all aspects of the use of the device and the specific environments in which it is intended to be used. Effectiveness would not have been able to be demonstrated without this thorough training program.

Usability: Usability: (i.e., ensuring that the end user can properly use the device) has been assessed by the following:

- The applicant validated the BrainPort V100 device training methods as described in the Training Manual and evaluated the effectiveness of the train-the trainer process as outlined in the "train-the-trainer" course syllabus.

- Trainers are professionals who have both credentials and practical experience working with the blind, such as: Certified Low Vision Specialists (CLVS), Certified Orientation and Mobility Specialist (COMS) and Teachers of the Visually Impaired (TVI).

- As part of the usability assessment, three quantifiable skills were tested to measure the validity of the BrainPort V100 device Training Manual techniques: 1) Freiberg Visual Acuity Test (FrACT test); 2) Object recognition (Table- top test); and 3) Orientation and Mobility (Hallway signs test).

- End user success was used to validate the effectiveness of the both the BrainPort V100 device Training Manual techniques and the train-the-trainer process. The training procedures used and validated by the applicant are thorough, task specific, and representative of the various types of environmental obstacles that a blind person may encounter in navigation both at home and in public places.

LABELING

The BrainPort V100 Trainer and User manuals are consistent with the clinical data and sufficiently cover the hazards and other clinically relevant information that may impact use of

the device. The labeling is sufficient and satisfies the requirements of 21 CFR §801.109 Prescription devices. The User manual is available in both print and audio formats.

The labeling includes the following information:

- Contraindications, warnings, precautions, and limitations needed for safe use of the device.
- A summary of the clinical performance testing, including adverse events and complications.
- Appropriate instructions for training and use of device.
- Product specifications and technical references specifications, including EMC compatibility and wireless technology information
- The potential risks associated with use of the device.

In addition, the labeling includes the following warnings that are specific to the risks associated with the use of IOD (tongue electrode array):

- Long-term use. Limited data are available on the long-term effects of electrical stimulation of the tongue. Long-term effects (beyond one year) have not been evaluated in clinical trials.
- Limited data is available on use of the device exceeding an average of between 250 and 400 minutes per BrainPort V100 User Manual 8 month, and a maximum of 1550 minutes per month. Wicab recommends that you tailor your use of the device to be within these time limits since long-term effects (beyond one year) exceeding this usage have not been evaluated in clinical trials.
- Oral Health. Limited data is available on stimulation sensitivity for individuals with oral conditions such as oral ulcerations, herpes simplex, oral thrush, and geographic tongue. If use of the device causes discomfort, discontinue use.
- Oral Health. Individuals with high, narrow palatal vaults should discontinue use of the device if use causes discomfort.
- Oral Health. Individuals with maxillary or mandibular tori that interfere with the IOD placement such that full contact with the tongue is prevented should seek additional training to gain the most benefit of the device.
- Dental Appliances (orthodontic appliances, removable partial or full dentures, lingual amalgam alloy restoration, metal crowns, etc.) Electrical stimulation of the tongue when metal appliances/surfaces are present may change results and/or cause unintended stimulation. If the stimulation causes discomfort, remove the IOD from your mouth and discontinue use of the device. If you notice a change in your dental device or appliance (warmth or looseness), discontinue the use of the device and contact your dentist.
- Dental Implants. The BrainPort device has not been thoroughly evaluated in the presence of dental implants. The safety of dental implants in BrainPort users is unknown. The use of this device potentially may cause heating of dental implants; chronic use of this device potentially may result in loosening and failure of dental implants.

RISKS TO HEALTH

Table 1 identifies the risks to health that may be associated with use of an oral electronic vision aid and the measures necessary to mitigate these risks.

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

SPECIAL CONTROLS

In combination with the general controls of the Food, Drug& Cosmetic 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).

BENEFIT/RISK DETERMINATION

The risks of the device are described above in the Summary of Clinical Information.

The risks of the device are based on non-clinical data as well as data collected from clinical studies described above.

Potential risks arising from the use of the BrainPort V100 include falls, allergic reaction to the materials in the device, tongue irritation from the electrodes or excessive stimulation and continuous electrical stimulation at a specific locus on the tongue along with the tissue damage that may occur (thus the perception of taste may change). Additionally, there is unknown potential risk associated with long-term use (e.g., damage to existing dental appliances worn and to dental implants due to potential long-term heating)

The probable benefits of the device are also based on data collected in clinical studies described above. The clinical information has demonstrated the effectiveness of BrainPort V100 in assisting profoundly blind (blind and visually impaired) individuals in object recognition and orientation and mobility activities. The BrainPort device demonstrates potential utility in assisting severely visually impaired and blind individuals in recognition of crude geometric and alphabetic shapes and characters, and as a potential augmentation tool to mobility and way finding tasks.

Additional factors considered in determining probable risks and benefits for the BrainPort V100 include: (1) the patient population is profoundly blind. The disease severity is not addressed by any form of currently-available treatment method, other than utilization of alternative assistive methods (such as a white cane or a guide dog). Therefore, tolerance of risk for benefit is not an issue. (2) Long-term safety and effectiveness data for the BrainPort V100 device are not available.

Given the available information above, the data support the conclusion that for aid in orientation, mobility, and object recognition, the probable benefits outweigh the probable risks for the BrainPort V100.

CONCLUSION

The *de novo* for the Brainport V100 is granted and the device is classified under the following:

Product Code: PIC
Device Type: Oral electronic vision aid
Class: II
Regulation: 21 CFR 886.5905