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## **NON-SURGICAL PRESCRIPTION VISION AID CLEARED BY FDA FOR USE BY PEOPLE WHO ARE PROFOUNDLY BLIND**

Middleton, WI, June 19, 2015

Wicab, Inc. announced today that the US Food and Drug Administration (FDA) granted Wicab's de novo application and allowed marketing of the BrainPort® V100 device in the USA. 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. It translates digital information from a video camera to gentle electrical stimulation patterns perceived as vibrations or tingling on the surface of the user's tongue. Users describe the experience as streaming images drawn on their tongue with small bubbles. With training, users are able to interpret the shape, size, location and position of objects in their environment, and to determine if objects are moving or stationary.

The safety and effectiveness of the BrainPort V100 were supported by clinical data including several assessments, such as object recognition, word identification, mobility, and safety assessments. The study demonstrated that 69% of trained users achieved success on the primary endpoint test of object recognition at 12 months. Users also successfully completed word identification and mobility tasks. A few users reported tingling, stinging, or a metallic taste associated with the device, but there were no serious device-related adverse events.

Robert Beckman, Wicab CEO, indicated the BrainPort V100 will initially be available at select training sites across the country. These centers of excellence will be located in metropolitan areas readily accessible for blind individuals and will provide comprehensive training on the use of the device. Training will be compulsory prior to purchasing a BrainPort V100 unit. The company plans to establish a demonstration program so that prospective customers can try the device for up to several days at a nominal cost, with no obligation to purchase the device. Wicab is simultaneously seeking philanthropic partners to help make this technology available to potential users that otherwise cannot afford to purchase the device.

“Potential advantages of the BrainPort V100 are that it can be used regardless of the cause or duration of blindness, and does not require an intact optic nerve in order to function,” explains Mr. Beckman, “Individuals blinded by congenital and acquired causes may use the BrainPort V100”. According to Mr. Beckman, “another potential advantage is its simplicity. Our non-surgical solution allows users to save their eyes, in case future research offers better alternatives for people who are totally blind.”

Additional information related to Wicab, Inc. and the BrainPort V100 device can be found on the company website, [www.wicab.com](http://www.wicab.com). Any specific questions related to sales or distribution of the device should be directed via email to [info@wicab.com](mailto:info@wicab.com).

Wicab, Inc. is a Wisconsin-based medical device company dedicated to providing innovative assistive devices for the blind based on sensory substitution technology originally developed by Dr. Paul Bach-y-Rita at the University of Wisconsin.

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