

FDA allows marketing of vision aid via tongue for blind

June 23 2015, by Nancy Owano



BrainPort V100

This month Wisconsin-based company Wicab announced that the US Food and Drug Administration cleared a nonsurgical vision aid for the profoundly blind. The safety and effectiveness of their product, BrainPort V100, were supported by clinical data.

An FDA press announcement on June 18 said the FDA "today allowed marketing of a new [device](#) that when used along with other assistive devices, like a cane or guide dog, can help orient people who are blind by helping them process visual images with their tongues."

What exactly is [BrainPort V100](#)? This is an oral electronic vision aid, said the company. It makes use of electro-tactile stimulation in orientation, mobility, and object [recognition](#).

The FDA described the components in the BrainPort V100 as "a battery-powered device that includes a video camera mounted on a pair of glasses and a small, flat intra-oral device containing a series of electrodes that the user holds against their tongue. Software converts the image captured by the video camera into electrical signals that are then sent to the [intra-oral device](#) and perceived as vibrations or tingling on the user's tongue."

This product does not replace a [guide dog](#) and cane; it is an "adjunctive" device to assistive methods such as dog and cane.

How does it work? The BrainPort V100's video camera mounted on sunglasses has an adjustable field of view (zoom). It translates digital information from a [video camera](#) to electrical stimulation patterns perceived as vibrations or tingling on the surface of the user's tongue. The tongue item is connected to the glasses by flexible cable.

A small hand-held unit provides user controls and houses a rechargeable battery. The system will run for approximately three hours on a single

charge.

"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."

With training and experience, said the FDA, the user learns to interpret the signals to determine the location, position, size, and shape of objects, and to determine if objects are moving or stationary.

Who can benefit? The BrainPort V100 has been tested by individuals with no usable vision, both congenitally blind and with acquired blindness. The company said, "Usually, users will have completed conventional blind rehabilitation and be comfortable using conventional assistive tools prior to starting BrainPort V100 [training](#)."

According to the FDA, clinical data supporting safety and effectiveness of the BrainPort V100 included assessments such as (1) object recognition and word identification and (2) oral health exams to determine risks associated with holding the intra-oral device in the mouth.

"Studies showed that 69 percent of the 74 subjects who completed one year of training with the device were successful at the [object recognition](#) test," said the FDA announcement. There were no serious device-related adverse events, said the FDA, though "Some patients reported burning, stinging or metallic taste associated with the intra-oral device."

The company's FAQ section commented, "People typically improve their device skills and abilities with [practice](#)." One learns to interpret the bubble-like patterns on the tongue as representative of objects in surroundings. Training will be required before purchasing a BrainPort

V100 unit.

"Medical device innovations like this have the potential to help millions of people," said William Maisel, M.D., M.P.H., deputy director for science and chief scientist in the FDA's Center for Devices and Radiological Health. "It is important we continue advancing device technology to help blind Americans live better, more independent lives."

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