FDA NEWS RELEASE

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FDA approves first retinal implant for adults with rare genetic eye disease

The U.S. Food and Drug Administration today approved the Argus II Retinal Prosthesis System, the first implanted device to treat adult patients with advanced retinitis pigmentosa (RP). The device, which includes a small video camera, transmitter mounted on a pair of eyeglasses, video processing unit (VPU) and an implanted retinal prosthesis (artificial retina), replaces the function of degenerated cells in the retina (a membrane inside the eye) and may improve a patient's ability to perceive images and movement. The VPU transforms images from the video camera into electronic data that is wirelessly transmitted to the retinal prosthesis.

RP is a rare genetic eye condition that damages the light-sensitive cells that line the retina. In a healthy eye, these cells change light rays into electrical impulses and send them through the optic nerve to the area of the brain that assembles the impulses into an image. In people with RP, the light-sensitive cells slowly degenerate resulting in gradual loss of side vision and night vision, and later of central vision. The condition can lead to blindness.

"This new surgically implanted assistive device provides an option for patients who have lost their sight to RP – for whom there have been no FDA-approved treatments," said Jeffrey Shuren, M.D., director of the FDA's Center for Devices and Radiological Health. "The device may help adults with RP who have lost the ability to perceive shapes and movement to be more mobile and to perform day-to-day activities."

The Argus II system is intended for use in adults, age 25 years or older, with severe to profound RP who have bare light perception (can perceive light, but not the direction from which it is coming) or no light perception in both eyes, evidence of intact inner layer retina function, and a previous history of the ability to see forms. Patients must also be willing and able to receive the recommended post-implant clinical follow-up, device fitting, and visual rehabilitation.

In addition to a small video camera and transmitter mounted on the glasses, the Argus II Retinal Prosthesis System has a portable video processing unit (VPU) and an array of electrodes that are implanted onto the patient's retina. The VPU transforms images from the video camera into electronic data that is wirelessly transmitted to the electrodes. The electrodes transform the data into electrical impulses that stimulate the retina to produce images. While the Argus II Retinal Prosthesis System will not restore vision to patients, it may allow them to detect light and dark in the environment, aiding them in identifying the location or movement of objects or people.

The FDA approved the Argus II Retinal Prosthesis System as a humanitarian use device, an approval pathway limited to those devices that treat or diagnose fewer than 4,000 people in the United States each year. To obtain approval for humanitarian use, a company must demonstrate a reasonable assurance that the device is safe and that its probable benefit outweighs the risk of illness or injury. The company also must show that there is no comparable device available to treat or diagnose the disease or condition.

The FDA reviewed data that included a clinical study of 30 study participants with RP who received the Argus II Retinal Prosthesis System. Investigators monitored participants for adverse events related to the device or to the implant surgery and regularly assessed their vision for at least two years after receiving the implant.

Results from the clinical study show that most participants were able to perform basic activities better with the Argus II Retinal Prosthesis System than without it. Some of the activities tested included locating and touching a square on a white field; detecting the direction of a motion; recognizing large letters, words, or sentences; detecting street curbs; walking on a sidewalk without stepping off; and matching black, grey and white socks.

Following the implant surgery, 19 of the 30 study patients experienced no adverse events related to the device or the surgery. Eleven study subjects experienced a total of 23 serious adverse events, which included erosion of the conjunctiva (the clear covering of the eyeball), dehiscence (splitting open of a wound along the surgical suture), retinal detachment, inflammation, and hypotony (low intraocular pressure).

Three government organizations provided support for the development of the Argus II. The Department of Energy, National Eye Institute at the National Institutes of Health and the National Science Foundation collaborated to provide grant funding totaling more than $100 million, support for material design and other basic research for the project.

Second Sight Medical Products, Inc. is based in Sylmar, Calif.

For more information

- Retinitis Pigmentosa[1]
- FDA Medical Devices[2]

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