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FDA Approves First Retinal Implant

US approval that gives hope to those with a rare genetic eye condition.

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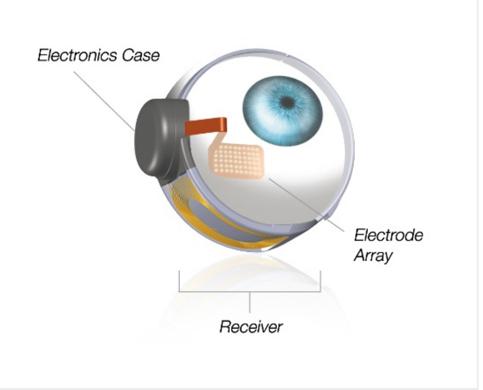

Second Sight's Argus II retinal implant.

The Food and Drug Administration (FDA) Thursday approved the first retinal implant for use in the United States. The FDA's green light for Second Sight's Argus II Retinal Prosthesis System gives hope to those blinded by a rare genetic eye condition called advanced retinitis pigmentosa, which damages the light-sensitive cells that line the retina.

For Second Sight, FDA approval follows more than 20 years of development, two clinical trials and more than $200 million in funding—half from the National Eye Institute, the Department of Energy and the National Science Foundation, and the rest from private investors. The Argus II has been approved for use in Europe since 2011 and implanted in 30 clinical-trial patients since 2007. The FDA's Ophthalmic Devices Advisory Panel in September 2012 voted unanimously to recommend approval.

The Argus II includes a small video camera, a transmitter mounted on a pair of eyeglasses, a video processing unit and a 60-electrode implanted retinal prosthesis that replaces the function of degenerated cells in the retina, the membrane lining the inside of the eye. Although it does not fully restore vision, this setup can improve a patient's ability to perceive images and movement, using the video processing unit to transform images from the video camera into electronic data that is wirelessly transmitted to the retinal prosthesis.

Retinitis pigmentosa—which affects about one in 4,000 people in the US and about 1.5 million people worldwide—kills the retina's photoreceptors, the rod and cone cells that convert light into electrical signals transmitted via the optic nerve to the brain's visual cortex for processing. Second Sight plans to adapt its technology to someday assist people afflicted with age-related macular degeneration, a similar but more common disease.

The company plans to make the Argus II available later this year in clinical centers throughout the US, cultivate a network of surgeons who can implant the device and recruit hospitals to offer it.

The Argus II is not the only retinal implant under development. Retina Implant AG takes a slightly different approach by making a prosthetic inserted beneath a portion of the retina. The company's technology is a three- by three-millimeter microelectronic chip (0.1-millimeter thick) containing about 1,500 light-sensitive photodiodes, amplifiers and electrodes surgically inserted beneath the fovea (which contains the cone cells) in the retina's macula region. The fovea enables the clarity of vision that people rely on to read, watch TV and drive. The chip helps generate at least partial vision by stimulating intact nerve cells in the retina. The nerve impulses from these cells are then led via the optic nerve to the visual cortex where they create impressions of sight. The chip's power source is positioned under the skin behind the ear and connected via a thin cable—no glasses or camera required. In May the company announced the first UK patients participating its latest trial had successfully received implants. To date surgeons have implanted Retina Implant prosthetics in 36 patients through two clinical trials over six years.

Stanford University researchers are in the early stages of developing self-powered retinal implants where each pixel in the device is fitted with silicon photodiodes. These sensors detect light, and control the output of a pulsed electrical current. Patients would wear goggles that emit near-infrared pulses that transmit both power and data directly to the photodiodes. Other retinal prosthesis are powered by inductive coils that, along with other components, must be surgically implanted in the patient's head. The researchers reported on the plausibility of their design in the May 2012 issue of Nature Photonics, describing in vitro electrical stimulation of healthy and degenerate rat retina by photodiodes powered by near-infrared light. (Scientific American is part of Nature Publishing Group.)

Weill Cornell Medical College researchers in New York City are taking retinal prosthetics in a different direction, having deciphered the neural codes that mouse and monkey retinas use to turn light patterns into patterns of electrical pulses that their brains translate into meaningful images. The researchers programmed this information into an “encoder” chip and combined it with a mini-projector to create an implantable prosthetic. The chip converts images that come into the eye into streams of electrical impulses, and the mini-projector then converts the electrical impulses into light impulses that are sent to the brain. Rather than increasing the number of electrodes placed in an eye to capture more information and send signals to the brain, this work focuses on the quality of the artificial signals themselves so as to improve their ability to carry impulses to the brain.

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