FDA Approves 'Bionic Eye' for Rare Vision Disorder

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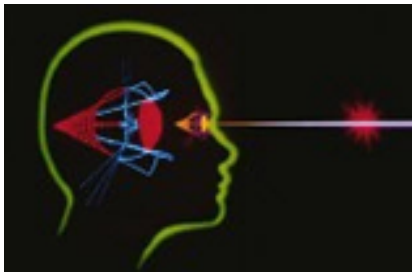

THURSDAY, Feb. 14 (HealthDay News) -- An implanted, sight-enhancing device some are calling a "bionic eye" is the first to gain approval for use in the United States, officials announced Thursday.

According to the U.S. Food and Drug Administration, the new Argus II Retinal Prosthesis System can help patients with a genetic eye disease called retinitis pigmentosa regain some sense of vision. About 100,000 Americans are believed to be affected by the illness, which causes a gradual deterioration of the eyes' photoreceptor cells.

The new device uses a tiny video camera attached to eyeglasses that transmits images to a sheet of electrode sensors that have been sewn into the patient's eye. These sensors then transmit those signals to the brain via the optic nerve. The device helps replace the damaged cells of the retina and helps patients see images or detect movement.

"It's a start, it's a beginning," said Dr. Mark Fromer, an ophthalmologist at Lenox Hill Hospital in New York City. "It's going to be exciting for people who get this device who are currently just seeing light or dark, [they] will see shapes and that will be life-altering for them."

An FDA official was similarly enthused.

"For many of the approximately 1,300 individuals who will develop the disease this year, this technology may change their lives," Dr. William Maisel, deputy director for science and chief scientist at FDA's Center for Devices and Radiological Health, said in an agency blog post. "It's the difference between night and day," he added.

Dr. Maisel's post also included testimony from people who had tested the device and spoke in favor of its approval at a recent FDA hearing:

"The biggest thing to me was being able to see the crosswalk lines on the street so I can safely cross streets in Manhattan," one user said.

"The most exciting day to me was October 27th, in 2009," another testified. "It was the first time I was able to see letters on the monitor screen [during a test of visual perception]. I had not seen letters since 1994, so that was huge."

A third person said he had a 17-year-old son, "and I don't mind telling you how much -- I mean, how happy that made me, not only to see the silhouette of my son, but to hear that voice coming and saying, 'Yeah, it's me, Dad. I'm here and I love you.'"

People with retinitis pigmentosa suffer damage to the light-sensitive cells of the retina. As these cells slowly degenerate, patients lose side vision and night vision and later on, central vision. The disease can cause blindness,

The FDA's approval is a limited one, labeled a "humanitarian use device" approval, meaning the Argus II can be used only for fewer than 4,000 patients per year.