Argus II Retinal Prosthesis System
Orion I Cortical Visual Prosthesis System (not yet approved)

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The Argus II Retinal Prosthesis System is an FDA approved visual prosthesis. The system consists of an implant, a small portable computer and a pair of glasses with a miniature video camera.

**Implant**

Our implant is an epiretinal (that is, the retinal surface is the site of stimulation) prosthesis that includes a receiver coil (antenna), electronics, and an electrode array. It is implanted in and around the eye. The array has 60 platinum gray electrodes arranged in a 6x10 grid. Each electrode is 200 μm (0.008”) in diameter. The array covers about 20° of visual field (diagonally). The flexible polymer thin-film electrode array, which follows the curvature of the retina, is attached to the retina over the macula with a retinal tack. The extra-ocular portion of the Argus II Implant is secured to the eye by means of a scleral band and sutures.

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**Figure 1:** Surgical implant as implanted schematic (surgical implantation is typically performed in 2 to 4 hours)

**Figure 2:** Electrode array. Current version contains 60 platinum gray electrodes
Figure 3: Surgical implant.

**Externals**

The external equipment consists of a pair of glasses and a video processing unit or VPU. The glasses include a miniature video camera and a transmitter coil. The Argus II Clinician Programming Kit is used to program the Argus II System stimulation parameters and video processing strategies for each patient. The software provides modules for electrode control, permitting the clinicians to program the amplitude, pulse-width, and frequency of the stimulation waveform of each electrode.

Figure 4: External Components of the Argus II System

**How it works**

In a healthy eye, the photoreceptors (rods and cones) on the retina convert light into tiny electrochemical impulses that are sent through the optic nerve and to the brain, where they are decoded
into images. If the photoreceptors no longer function correctly (as in RP and AMD), the first step in this process is disrupted and the visual system cannot transform light into images, causing blindness. The Argus II System is designed to bypass damaged photoreceptors altogether and provides real-time visual information to blind patients. The miniature video camera captures a scene and the video is sent to the small VPU where it is processed and transformed into instructions that are sent back to the glasses. These instructions are transmitted wirelessly to the receiver coil in the implant. The signals are then sent to the electrode array, which emits small pulses of electricity. These pulses bypass the damaged photoreceptors and stimulate the retina’s remaining cells, which transmit the visual information along the optic nerve to the brain. This process is intended to create the perception of patterns of light which patients can learn to interpret as real-time visual patterns.

Figure 5: The patient perceives patterns of light created by electrical stimulation.

The Argus II System has been extensively tested at the component, sub-assembly, and system levels for long term reliability. The hermetic electronics case has been demonstrated to prevent moisture accumulation inside the device for many years. The Argus II implant is specified to last a minimum of five years, however, in vitro tests and actual clinical data suggest the device should last much longer. Production implants have reached more than ten years of lifetime use in accelerated in vitro testing and more than seven years use in real time in patients under active stimulation and normal use conditions.
Exhibit D

Argus II
   Surgical Manual
   Fitting Manual
   User Manual

Physical specifications, electrical specifications, programming parameters and other technical support related to Argus II and Orion I, as agreed to in a CRA.