

## **FDA panel recommends approval for Second Sight's 'bionic eye'**

Mass Device

And FDA advisory panel recommends that the federal watchdog agency approve a humanitarian device exemption for Second Sight's Argus II "bionic eye" retinal implant.



An FDA advisory panel recommended approval for a "bionic eye" designed to restore sight for the blind.

The FDA's Ophthalmic Devices Panel voted 17-2 that the Argus II device's benefits outweigh any potential risks; 18-1 that a clinical trial demonstrated "a reasonable assurance of safety;" and was unanimously agreed that the proposed minimum age requirement of 25 years is appropriate.

The "bionic eye," which uses a head-worn camera to capture a scene and process it into electrical signals that are then sent to the cells in the eye, [may pose long-term risks that increase over time](#) [1], according to panel documents released ahead of the meeting. Nevertheless, the panel agreed that the federal watchdog agency ought to grant a humanitarian device exemption for the Argus II retinal prosthesis.

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<http://www.mdtmag.com/news/2012/09/fda-panel-recommends-approval-second-sights-bionic-eye>

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[1] <http://www.massdevice.com/news/safety-concerns-may-stymie-fda-approval-1st-its-kind-retinal-prosthesis?page=show>

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Published on Medical Design Technology (<http://www.mdtmag.com>)

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