Humanitarian Device Exemption (HDE)

Note: this medical device has supplements. The device description may have changed. Be sure to look at the supplements to get an up-to-date view of this device.

Trade Name	ARGUS II RETINAL PROSTHESIS SYSTEM
Classification Name	Prosthesis, Retinal[23]
Generic Name	Prosthesis, Retinal
Applicant	SECOND SIGHT, LLC. 12744 San Fernando Rd. Building 3 Sylmar, CA 91342
HDE Number	H110002
Date Received	05/04/2011
Decision Date	02/13/2013
Product Code	NBF [Registered Establishments With NBF[24]]
Docket Number	M-0205
Notice Date	02/13/2013
Advisory Committee	Ophthalmic
Clinical Trials	NCT00407602[25]
Supplement Type	Hde Original
Expedited Review Granted?	No
Combination Product	No

Approval Order Statement

Approval for the argus™ ii retinal prosthesis system. This device is indicated for use in patients with severe to profound retinitis pigmentosa who meet the following criteria:1) adults, age 25 years or older; 2) bare light or no light perception in both eyes (if the patient has no residual light perception, then evidence of intact inner layer retina function must be confirmed.); 3) previous history of useful form vision; 4) aphakic or pseudophakic (if the patient is phakic prior to implant, the natural lens willbe removed during the implant procedure.); and 5) patients who are willing and able to receive the recommended post-implant clinical follow-up, device fitting, and visual rehabilitation. The argus ii implant is intended to be implanted in a single eye, typically the worse-seeing eye.

Approval Order Summary	Approval Order[26] Summary Of Safety And Probable Benefit[27]
Labeling	Labeling[28]
Post-Approval Study Supplements:	Show Report Schedule And Study Progress[29] S001[30] S002[31] S003[32] S004[33] S005[34] S006[35] S007[36] S009[37] S010[38] S011[39] S012[40] S013[41] S014[42] S015[43] S016[44] S017[45] S018[46] S019[47] S020[48] S021[49] S022[50] S023[51] S024[52] S026[53] S028[54] S029[55] S031[56]

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