CustomFlex™ Artificial Iris - P170039

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: CustomFlex™ Artificial Iris
PMA Applicant: Clinical Research Consultants, Inc.
Address: 3308 Jefferson Avenue, Cincinnati, OH 45220
Approval Date: May 30, 2018
Approval Letter: https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170039a.pdf (https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170039a.pdf)

What is it? The CustomFlex Artificial Iris is a prosthetic iris (the colored part of the eye around the pupil) made of thin, foldable medical-grade silicone. This device is custom-made and can be sized and colored for each individual patient. The CustomFlex Artificial Iris can be used to treat congenital (genetic disorder in which the iris is completely or partially absent) and traumatic aniridia.It can also be used to treat iris defects due to other reasons or conditions, such as albinism, or surgical removal due to melanoma.

How does it work? A surgeon makes a small incision and implants the CustomFlex Artificial Iris under the incision. The CustomFlex Artificial Iris is held in place by the anatomical structures of the eye or, if needed, by sutures, and mimics the function of the natural iris.The CustomFlex Artificial Iris creates an artificial pupil that reduces the amount of light entering the eye.

When is it used? The CustomFlex Artificial Iris is used to treat aniridia, an eye disorder associated with a complete or partial absence of the iris.

What will it accomplish? Patients have reported that the CustomFlex Artificial Iris can produce a clinically meaningful reduction of day-and night-time light sensitivity and disabling glare, improve the cosmetic appearance of the eye, and may contribute to an increase in vision-related quality of life.

When should it not be used? The CustomFlex Artificial Iris should not be used in patients who have any of the following:

- active eye infection or uncontrolled inflammation of the eye (such as acute or severe chronic uveitis)
- eye disorder (other than aniridia) that causes the eye to be abnormal in size, shape or function (such as microphthalmus or rubella cataract)
- untreated eye disorder that is potentially vision-threatening (such as an untreated retinal detachment or untreated chronic glaucoma)
- disease process in which new blood vessels grow abnormally on the iris (rubeosis of the iris)
- a complication of diabetes in which new blood vessels grow on the surface of the retina or elsewhere (proliferative diabetic retinopathy)
- inherited disease that causes cells in the main focusing area of the retina (Stargardt's retinopathy)
- pregnancy

Additional information (including warnings, precautions, and adverse events): Summary of Safety and Effectiveness Data (SSED) and labeling (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P170039) are available online.

- Summary of Safety and Effectiveness Data (SSED) (https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170039b.pdf)
- Labeling (Patient) (https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170039c.pdf)
- Labeling (Professional) (https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170039d.pdf)