FDA

Post-Approval Studies (PAS) Database

The FDA has the authority to require sponsors to perform a post-approval study (or studies) at the time of approval of a premarket approval (PMA), humanitarian device exemption (HDE), or product development protocol (PDP) application. Post-approval studies can provide patients, health care professionals, the device industry, the FDA and other stakeholders information on the continued safety and effectiveness (or continued probable benefit, in the case of an HDE) of approved medical devices. This database allows you to search Post-Approval Study information by applicant or device information.

Learn more...[6]

Pediatric New Enrollment

General

Study Status	**Delayed**
Application Number / Requirement Number	P170039 / PAS002
Date Original Protocol Accepted	10/03/2019
Date Current Protocol Accepted	
Study Name	Pediatric New Enrollment
Device Name	CustomFlex Artificial Iris
Clinical Trial Number(s)[7]	NCT01860612[8]

General Study Protocol Parameters

Study Design	Prospective Cohort Study
Data Source	New Data Collection
Comparison Group	Device Subjects Serve as Own Control
Analysis Type	Descriptive
Study Population	Child: 2 yrs < 12 yrs, Adolescent: 13-18 yrs, Transit.Adolescent A (distinctively):18 yrs<22 yrs

Detailed Study Protocol Parameters

Study Objectives	Prospective, non-masked, multicenter study to determine the long-term (60 months) safety and effectiveness of the CustomFlex™ Artificial Iris for the treatment of full or partial iris defects in pediatric subjects. The study will include follow-up data for up to 5 years from previously enrolled pediatric subjects who participated in the 12-month AI-001 IDE study and are participating in the AI-001 extended follow-up PAS (P170039/S001). In addition, this study will include additional newly enrolled pediatric subjects.
Study Population	The study includes the implanted subjects. There is no control arm. The postoperative outcomes are compared to their preoperative baseline.
Sample Size	The Pediatric New Enrollment Cohort will include enrollment of up to 125 additional pediatric eyes (depending on how many pediatric eyes are enrolled in the ODE led PAS), meeting all of the inclusion and exclusion criteria below, to provide a total of 125 treated pediatric eyes when the Pediatric New Enrollment Cohort is combined with the Pediatric Rollover Cohort. Treating a total of up to 125 pediatric eyes will ensure that ~100 pediatric eyes will be available for assessment at 5 years postoperatively.

Key Study Endpoints	The primary study outcome is to evaluate device related adverse events (AEs) postoperatively at Month 60. The secondary study outcome is to evaluate the cumulative rate of intraocular lens (IOL)-related AEs at Month 60. Other outcomes: Secondary surgical interventions, implant position, device or surgery related complications, and device malfunctions or defects. Outcomes that will be evaluated include, but are not limited to: Cumulative AEs Endothelial cell density (ECD) changes Device malfunction or defects Device related complications
Follow-up Visits and Length of Follow-up	60 months

Interim or Final Data Summary

Actual Number of Patients Enrolled	0
Actual Number of Sites Enrolled	4

Pediatric New Enrollment Reporting Schedule

Reporting Schedule	Report Date Due	FDA Receipt Date	Applicant's Reporting Status
6 month report	11/28/2018	12/27/2018	Overdue/Received
1 year report	05/30/2019	05/30/2019	On Time
18 month report	11/28/2019	01/30/2020	Overdue/Received
2 year report	05/29/2020	05/28/2020	On Time
3 year report	05/29/2021	06/01/2021	Overdue/Received
4 year report	05/29/2022	06/02/2022	Overdue/Received
5 year report	05/29/2023	06/01/2023	Overdue/Received
66 month report	09/01/2023	09/13/2023	Overdue/Received
6 year report	05/29/2024	06/07/2024	Overdue/Received
7 year report	05/29/2025	05/30/2025	Overdue/Received
8 year report	07/30/2026	08/03/2026	Overdue/Received

Contact Us

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Food and Drug Administration
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Silver Spring, MD 20993-0002
Email: MandatedStudiesPrograms@fda.hhs.gov

Additional Resources

- Guidance Document: "Procedures for Handling Post-Approval Studies Imposed by PMA Order"[9]
- PAS Program Background[10]

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