FDA 510(k) Premarket Notification

K240058 AEYE-DS

CLEARED

Apr 23, 2024
106 days to decision

K240058 · Product code: **PIB** · Ophthalmic
Source: https://www.510kdatabase.net/k240058/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diabetic Retinopathy Detection Device (PIB)
Date received	Jan 8, 2024
Decision date	Apr 23, 2024
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Aeye Health, Inc.**
Location	New York, NY, US
Contact	Zack Dvey-Aharon
510(k) history	2 submissions · 2 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	**A. Stein - Regulatory Affairs Consulting , Ltd.**
Contact	Ahava Stein

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT05857943

Efficacy and Safety of AEYE-DS Software Device for Automated Detection of Diabetic Retinopathy From Digital Funduscopic Images

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	363 patients (actual)
Study sites	3 sites
Condition studied	Diabetes Mellitus; Diabetic Retinopathy
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Oct 10, 2023
Sponsor	AEYE Health Inc (Industry)

Primary outcome

Sensitivity and Specificity

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05857943