FDA 510(k) Premarket Notification

K221183 AEYE-DS

CLEARED

Nov 10, 2022
199 days to decision

K221183 · Product code: **PIB** · Ophthalmic
Source: https://www.510kdatabase.net/k221183/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diabetic Retinopathy Detection Device (PIB)
Date received	Apr 25, 2022
Decision date	Nov 10, 2022
Days to decision	199 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	**Hogan Lovells US LLP**
Contact	John Smith

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

CLINICAL EVIDENCE - NCT04612868

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

Status	Completed
Enrollment	531 patients (actual)
Study sites	1 site
Condition studied	Diabetes Mellitus; Diabetic Retinopathy
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Dec 26, 2021
Sponsor	AEYE Health Inc (Industry)

Primary outcome

Sensitivity and Specificity, Based on Two Macula-centered Images (One Image From Each Eye of the Patient)

Secondary outcome

Sensitivity and Specificity, Based on Four Images (One Macula Centered Image and One Optic Disc Centered Image Per Eye)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04612868