FDA 510(k) Premarket Notification

K223357 EyeArt v2.2.0

CLEARED

Jun 16, 2023
226 days to decision

K223357 · Product code: **PIB** · Ophthalmic
Source: https://www.510kdatabase.net/k223357/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diabetic Retinopathy Detection Device (PIB)
Date received	Nov 2, 2022
Decision date	Jun 16, 2023
Days to decision	226 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Eyenuk, Inc.**
Location	Los Angeles, CA, US
Contact	Kaushal Solanki
510(k) history	2 submissions · 2 cleared · 2020-2023

CLINICAL EVIDENCE - NCT03112005

Assessment of EyeArt as an Automated Diabetic Retinopathy Screening Tool

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	942 patients (actual)
Study sites	1 site
Condition studied	Diabetic Retinopathy; Diabetic Eye Problems; Diabetic Macular Edema
Study type	Observational
Completion date	May 31, 2018
Sponsor	Eyenuk, Inc. (Industry)

Primary outcome

Number of subject eyes whose EyeArt results match the reading center grading for identifying referable diabetic eye disease (moderate NPDR or higher on the ICDR scale or surrogate markers for CSME).

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03112005