

K243819 LuminopiaApr 9, 2025
118 days to decisionK243819 · Product code: **QQU** · Ophthalmic
Source: <https://www.510kdatabase.net/k243819/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Digital Therapy Device For Amblyopia (QQU)
Date received	Dec 12, 2024
Decision date	Apr 9, 2025
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Luminopia, Inc.
Location	Cambridge, MA, US
Contact	Scott Xiao
510(k) history	4 submissions · 3 cleared · 2021-2025

CLINICAL EVIDENCE - NCT06429280

Clinical Data Registry of Amblyopia Patients on Luminopia Treatment

Status	Recruiting - <i>No results published to ClinicalTrials.gov</i>
Enrollment	500 patients (estimated)
Study sites	13 sites
Condition studied	Amblyopia
Study type	Observational
Completion date	Dec 31, 2026
Sponsor	Luminopia (Industry)

Primary outcome

Change in Visual Acuity from baseline to consecutive visits

Secondary outcome

Visual Acuity analyses will also be conducted by Prior Treatment

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06429280
