K222484 Retitrack

CLEARED

May 9, 2023
265 days to decision

K222484 · Product code: **HLL** · Ophthalmic
Source: https://www.510kdatabase.net/k222484/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Eye Movement (HLL)
Date received	Aug 17, 2022
Decision date	May 9, 2023
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**C. Light Technologies, Inc.**
Location	Medford, MA, US
Contact	Christy K Sheehy-Bensinger
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Blur Product Development**
Contact	Christy Coleman

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

CLINICAL EVIDENCE - NCT05222022

Engineering Evaluation of an Eye Movement Monitor Device

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	39 patients (actual)
Study sites	1 site
Condition studied	Healthy
Primary purpose	Basic_science
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Oct 10, 2023
Sponsor	C. Light Technologies, Inc. (Industry)

Primary outcome

Device measurement of involuntary fixational microsaccade amplitude

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05222022