FDA 510(k) Premarket Notification

K221375 CureSight-CS100

CLEARED

Sep 29, 2022
140 days to decision

K221375 · Product code: **QQU** · Ophthalmic
Source: https://www.510kdatabase.net/k221375/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Digital Therapy Device For Amblyopia (QQU)
Date received	May 12, 2022
Decision date	Sep 29, 2022
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Novasight , Ltd.**
Location	Airport City, IL
Contact	Ran Yam
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Regulatory Pathways Group, Inc.**
Contact	Lee Kramm

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

CLINICAL EVIDENCE - NCT05185076

Treatment for Amblyopia Under Binocular Conditions Versus the Standard of Care, Monocular Deprivation Treatment

Status	Unknown - *No results published to ClinicalTrials.gov*
Enrollment	114 patients (actual)
Study sites	2 sites
Condition studied	Amblyopia
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Single blind
Completion date	May 1, 2022
Sponsor	NovaSight (Industry)

Primary outcome

best corrected visual acuity

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05185076