FDA 510(k) Premarket Notification

K203594 EyeCTester

CLEARED

Sep 7, 2022
637 days to decision

K203594 · Product code: **QTW** · Ophthalmic
Source: https://www.510kdatabase.net/k203594/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Digital Amsler Grid (QTW)
Date received	Dec 9, 2020
Decision date	Sep 7, 2022
Days to decision	637 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neuro-Eye Diagnostic Systems, LLC**
Location	Houston, TX, US
Contact	Jade S. Schiffman
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Proxima Clinical Research, Inc.**
Contact	Isabella Schmitt

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

CLINICAL EVIDENCE - NCT04607369

Implementation of the NEDS EyeCTester App

Status	Enrolling by invitation - *No results published to ClinicalTrials.gov*
Enrollment	100 patients (estimated)
Study sites	1 site
Condition studied	Optic Nerve Disease; Macular Disease; Visual Pathway Disorder
Study type	Observational
Completion date	Dec 31, 2028
Sponsor	Neuro-Eye Diagnostic Systems, LLC (Industry)

Primary outcome

Primary Outcome Measure for Groups 4a and 4b:

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04607369