FDA 510(k) Premarket Notification

K253586 RM Electrode (RMH 25-01)

CLEARED

Apr 1, 2026
135 days to decision

K253586 · Product code: **HLZ** · Ophthalmic
Source: https://www.510kdatabase.net/k253586/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Corneal (HLZ)
Date received	Nov 17, 2025
Decision date	Apr 1, 2026
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Retmap, Inc.**
Location	Chicago, IL, US
Contact	Shresta Patangay
510(k) history	2 submissions · 2 cleared · 2023-2026

CLINICAL EVIDENCE - NCT05509608

Evaluating a New Sensor That Measures the Health of the Retina in Normally-sighted Subjects

Status	Enrolling by invitation - *No results published to ClinicalTrials.gov*
Enrollment	90 patients (estimated)
Study sites	2 sites
Condition studied	Electrode Site Reaction
Primary purpose	Other
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Dec 31, 2025
Sponsor	RetMap, Inc (Industry)

Primary outcome

Arm1: ERG signal quality, including peak amplitudes, noise levels, and signal to noise ratios.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05509608