

K251353 Eyer 2Jan 16, 2026
261 days to decisionK251353 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k251353/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Apr 30, 2025
Decision date	Jan 16, 2026
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Phelcom Technologies
Location	S?o Carlos, BR
Contact	Flávio Pascoal Vieira
510(k) history	2 submissions · 2 cleared · 2023-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251353/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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