

K221329 Eyer Retinal Camera NM-STDFeb 22, 2023
292 days to decisionK221329 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k221329/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	May 6, 2022
Decision date	Feb 22, 2023
Days to decision	292 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

REGULATORY CONSULTANT

Consulting firm	Passarini Regulatory Affairs of America, LLC
Contact	Bruno Milhoci de Souza

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

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