FDA 510(k) Premarket Notification

K221329 Eyer Retinal Camera NM-STD

CLEARED

Feb 22, 2023
292 days to decision

K221329 · 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