FDA 510(k) Premarket Notification

K250683 Resolve Fundus Camera

CLEARED

Apr 30, 2025
55 days to decision

K250683 · Product code: **HKI** · Ophthalmic
Source: https://www.510kdatabase.net/k250683/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Mar 6, 2025
Decision date	Apr 30, 2025
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Optain Health, Inc.**
Location	New York, NY, US
Contact	Emilia Gonzalez
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Oconnell Regulatory Consultants, Inc.**
Contact	Maureen OConnell

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