FDA 510(k) Premarket Notification

# K250770 Optina-4C (MHRC-C1N)

**CLEARED**

Sep 4, 2025
175 days to decision

K250770 · Product code: **HKI** · Ophthalmic
Source: https://www.510kdatabase.net/k250770/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Camera, Ophthalmic, Ac-powered (HKI) |
| Date received | Mar 13, 2025 |
| Decision date | Sep 4, 2025 |
| Days to decision | 175 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Optina Diagnostics, Inc.** |
| Location | Montreal, CA |
| Contact | Sarah Lemaire |
| 510(k) history | 2 submissions · 2 cleared · 2023-2025 |

## CLINICAL EVIDENCE - NCT05903651

### Retinal Deep PhenotypingTM

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|---|---|
| Status | Completed - *No results published to ClinicalTrials.gov* |
| Enrollment | 813 patients (actual) |
| Study sites | 2 sites |
| Condition studied | Healthy |
| Study type | Observational |
| Completion date | Mar 14, 2024 |
| Sponsor | Optina Diagnostics Inc. (Industry) |

**Primary outcome**

At least one (1) pre-trained DL model from hyperspectral retinal images.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05903651