

K231230 Optina-4C (MHRC-C1N)Dec 5, 2023
221 days to decisionK231230 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k231230/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Apr 28, 2023
Decision date	Dec 5, 2023
Days to decision	221 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231230/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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