

K243664 Sentinel CameraDec 17, 2024
20 days to decisionK243664 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k243664/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Nov 27, 2024
Decision date	Dec 17, 2024
Days to decision	20 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ai Optics
Location	New York, NY, US
Contact	Andrew DiGiore
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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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