

**K053044 OPTO GLOBAL DIGITAL FUNDUS CAMERA SYSTEM
MODEL ADS 1.5**Jan 24, 2006
88 days to decisionK053044 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k053044/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Oct 28, 2005
Decision date	Jan 24, 2006
Days to decision	88 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Opto Global, Inc.
Location	Granite Bay, CA, US
Contact	MARK T FUKUHARA
510(k) history	1 submissions · 1 cleared · 2006-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k053044/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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