

K973218 NIDEK HANDYNov 4, 1997
69 days to decisionK973218 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k973218/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Aug 27, 1997
Decision date	Nov 4, 1997
Days to decision	69 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Nidek, Inc.
Location	Mchenry, IL, US
Contact	KEN KATO
510(k) history	77 submissions · 77 cleared · 1983-2005

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