

K973533 NIDEK STEREO DISC CAMERA(3-DX)/NIDEK STEREO FUNDUS CAMERA(3-DXF)

Nov 4, 1997
47 days to decision

K973533 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k973533/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Sep 18, 1997
Decision date	Nov 4, 1997
Days to decision	47 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k973533/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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