

**K113451 NON-MYDRIATIC AUTO FUNDUS CAMERA AFC-330
WITH IMAGE FILING SOFTWARE NA VIS-EX**May 8, 2012
169 days to decisionK113451 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k113451/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Nov 21, 2011
Decision date	May 8, 2012
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nidek Technologies Srl
Location	Lake Forest, CA, US
Contact	ENRICO BISSON
510(k) history	5 submissions · 5 cleared · 2001-2012

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