

K003299 OPD-SCAN, MODELS ARK-10000 AND ARK-9000Mar 9, 2001
140 days to decisionK003299 · Product code: **HLQ** · Ophthalmic
Source: <https://www.510kdatabase.net/k003299/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Keratoscope, Ac-powered (HLQ)
Date received	Oct 20, 2000
Decision date	Mar 9, 2001
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nidek Co., Ltd.
Location	Lake Forest, CA, US
Contact	CAROL PATTERSON
510(k) history	20 submissions · 19 cleared · 2001-2023

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