

K013337 PRIZM KERATOME BLADE (NIDEK MODEL), MODEL MK8514NIDec 13, 2001
65 days to decisionK013337 · Product code: **HNO** · Ophthalmic
Source: <https://www.510kdatabase.net/k013337/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Keratome, Ac-powered (HNO)
Date received	Oct 9, 2001
Decision date	Dec 13, 2001
Days to decision	65 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Surgin, Inc.
Location	Tustin, CA, US
Contact	DON HAAR
510(k) history	1 submissions · 1 cleared · 2001-2001

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