FDA 510(k) Premarket Notification

K990900 MICROKERATOME, MODEL MK-2000

CLEARED

Sep 24, 1999
190 days to decision

K990900 · Product code: **HNO** · Ophthalmic
Source: https://www.510kdatabase.net/k990900/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Keratome, Ac-powered (HNO)
Date received	Mar 18, 1999
Decision date	Sep 24, 1999
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k990900/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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