FDA 510(k) Premarket Notification

K831083 AUTO REFRACTOMETER

CLEARED

Jun 10, 1983
67 days to decision

K831083 · Product code: **HKO** · Ophthalmic
Source: https://www.510kdatabase.net/k831083/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Refractometer, Ophthalmic (HKO)
Date received	Apr 4, 1983
Decision date	Jun 10, 1983
Days to decision	67 days
Third-party review	No

APPLICANT

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