FDA 510(k) Premarket Notification

K950794 STREAK RETINOSCOPE RX-RC

CLEARED

Mar 28, 1995
35 days to decision

K950794 · Product code: **HKM** · Ophthalmic
Source: https://www.510kdatabase.net/k950794/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Retinoscope, Battery-powered (HKM)
Date received	Feb 21, 1995
Decision date	Mar 28, 1995
Days to decision	35 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Neitz Instruments Company, Ltd.**
Location	Washington, DC, US
Contact	YASUO KAWANO
510(k) history	24 submissions · 24 cleared · 1994-1997