FDA 510(k) Premarket Notification

K972440 CATARACTSCREENER CT - S

CLEARED

Sep 30, 1997
92 days to decision

K972440 · Product code: **HKI** · Ophthalmic
Source: https://www.510kdatabase.net/k972440/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Jun 30, 1997
Decision date	Sep 30, 1997
Days to decision	92 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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