FDA 510(k) Premarket Notification

K941234 NON-MYDRIATIC RETINAL CAMERA

CLEARED

Jun 7, 1995
449 days to decision

K941234 · Product code: **HKI** · Ophthalmic
Source: https://www.510kdatabase.net/k941234/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Mar 15, 1994
Decision date	Jun 7, 1995
Days to decision	449 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Canon USA, Inc.**
Location	Mchenry, IL, US
Contact	HIROYUKI TAKAHASHI
510(k) history	48 submissions · 48 cleared · 1984-2009