FDA 510(k) Premarket Notification

K003236 RETINADX

CLEARED

Nov 2, 2000
16 days to decision

K003236 · Product code: **HKI** · Ophthalmic
Source: https://www.510kdatabase.net/k003236/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Oct 17, 2000
Decision date	Nov 2, 2000
Days to decision	16 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Regulatory Associates, Inc.**
Location	Lakewood, CO, US
Contact	Kevin Walls
510(k) history	1 submissions · 1 cleared · 2000-2000