FDA 510(k) Premarket Notification

K022164 ZETA DIAGNOSTIC RETINAL IMAGING SYSTEM

CLEARED

Jul 26, 2002
23 days to decision

K022164 · Product code: **HKI** · Ophthalmic
Source: https://www.510kdatabase.net/k022164/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Jul 3, 2002
Decision date	Jul 26, 2002
Days to decision	23 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Zeta Development Laboratories**
Location	El Dorado Hills, CA, US
Contact	MARK T FUKUHARA
510(k) history	1 submissions · 1 cleared · 2002-2002