FDA 510(k) Premarket Notification

K083387 MODIFICATION TO KOWA NONMYD ALPHA-DIII

CLEARED

Jan 16, 2009
60 days to decision

K083387 · Product code: **HKI** · Ophthalmic
Source: https://www.510kdatabase.net/k083387/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Nov 17, 2008
Decision date	Jan 16, 2009
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Kowa Co. , Ltd.**
Location	Rockville, MD, US
Contact	AKIHIRO FUJITA
510(k) history	16 submissions · 16 cleared · 2005-2014