FDA 510(k) Premarket Notification

K091098 KOWAGENESIS-DF

CLEARED

Aug 7, 2009
113 days to decision

K091098 · Product code: **HKI** · Ophthalmic
Source: https://www.510kdatabase.net/k091098/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Apr 16, 2009
Decision date	Aug 7, 2009
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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