FDA 510(k) Premarket Notification

K191945 KOWA nonmyd 8

CLEARED

Sep 10, 2019
50 days to decision

K191945 · Product code: **HKI** · Ophthalmic
Source: https://www.510kdatabase.net/k191945/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Jul 22, 2019
Decision date	Sep 10, 2019
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Kowa Company , Ltd.**
Location	Chofu-Shi, JP
Contact	Nariaki Morita
510(k) history	3 submissions · 3 cleared · 2019-2022