FDA 510(k) Premarket Notification

K133892 IVUE 500

CLEARED

Mar 19, 2014
89 days to decision

K133892 · Product code: **HLI** · Ophthalmic
Source: https://www.510kdatabase.net/k133892/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Ac-powered (HLI)
Date received	Dec 20, 2013
Decision date	Mar 19, 2014
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Optovue, Inc.**
Location	Fremont, CA, US
Contact	MICHAEL J SARRASIN
510(k) history	16 submissions · 16 cleared · 2006-2022