

K150722 EnFocus 2300, EnFocus 4400Dec 2, 2015
257 days to decisionK150722 · Product code: **HLI** · Ophthalmic
Source: <https://www.510kdatabase.net/k150722/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Ac-powered (HLI)
Date received	Mar 20, 2015
Decision date	Dec 2, 2015
Days to decision	257 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bioptigen, Inc.
Location	Washington, DC, US
Contact	Tammy B Carrea
510(k) history	4 submissions · 4 cleared · 2006-2016

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