

K063343 BIOPTIGEN SPECTRAL DOMAIN OPHTHALMIC IMAGING SYSTEMDec 13, 2006
37 days to decisionK063343 · Product code: **HLI** · Ophthalmic
Source: <https://www.510kdatabase.net/k063343/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Ac-powered (HLI)
Date received	Nov 6, 2006
Decision date	Dec 13, 2006
Days to decision	37 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

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