

K120057 ENVISU SPECTRAL DOMAIN OPHTHALMIC IMAGING SYSTEM (SDOIS)

May 11, 2012
123 days to decision

K120057 · Product code: **HLI** · Ophthalmic
Source: <https://www.510kdatabase.net/k120057/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Ac-powered (HLI)
Date received	Jan 9, 2012
Decision date	May 11, 2012
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bioptigen, Inc.
Location	Washington, DC, US
Contact	DAWN REILLY-O'DELL
510(k) history	4 submissions · 4 cleared · 2006-2016

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k120057/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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