

**K101223 SPECTRALIS HRA+OCT, SPECTRALIS FA_OCT,
SPECTRALIS ICGA+ OCT, SPECTRALIS HRA, SPECTRALIS FA**Oct 1, 2010
151 days to decisionK101223 · Product code: **OBO** · Ophthalmic
Source: <https://www.510kdatabase.net/k101223/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	May 3, 2010
Decision date	Oct 1, 2010
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Heidelberg Engineering
Location	Carlsbad, CA, US
Contact	DIANE MANDELL-HORWITZ
510(k) history	9 submissions · 9 cleared · 1991-2010

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