

**K121993 SPECTRALIS HRA + OCT AND VARIANTS,  
SPECTRALIS FA+ OCT, SPECTRALIS ICGA +OCT,  
SPECTRALIS OCT BLUE PEAK, SPECTRALIS OCT**Oct 25, 2012  
111 days to decisionK121993 · Product code: **OBO** · Ophthalmic  
Source: <https://www.510kdatabase.net/k121993/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Jul 6, 2012
Decision date	Oct 25, 2012
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Heidelberg Engineering GmbH</b>
Location	Heidelberg, DE
Contact	DIANE HORWITZ, PH.D.
510(k) history	16 submissions · 16 cleared · 2011-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121993/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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