

**K152205 Spectralis HRA + OCT and variants (e.g.s below),  
Spectralis FA+OCT, Spectralis ICGA+OCT, Spectralis OCT Blue  
Peak, Spectralis OCT ith Multicolor**May 6, 2016  
274 days to decisionK152205 · Product code: **OBO** · Ophthalmic  
Source: <https://www.510kdatabase.net/k152205/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Aug 6, 2015
Decision date	May 6, 2016
Days to decision	274 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Heidelberg Engineering GmbH</b>
Location	Heidelberg, DE
Contact	Gerhard Zinser
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/k152205/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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