

K201252 Spectralis HRA+OCT and variantsSep 9, 2020
121 days to decisionK201252 · Product code: **OBO** · Ophthalmic
Source: <https://www.510kdatabase.net/k201252/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	May 11, 2020
Decision date	Sep 9, 2020
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Heidelberg Engineering GmbH
Location	Heidelberg, DE
Contact	Christoph Schoess
510(k) history	16 submissions · 16 cleared · 2011-2025

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