

K163195 PRIMUSJun 21, 2017
218 days to decisionK163195 · Product code: **OBO** · Ophthalmic
Source: <https://www.510kdatabase.net/k163195/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Nov 15, 2016
Decision date	Jun 21, 2017
Days to decision	218 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Carl Zeiss Suzhou Co., Ltd.
Location	Suzhou, CN
Contact	Huang XiaoDong
510(k) history	2 submissions · 2 cleared · 2017-2018

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