

**K200516 OCT-Camera ID 21101A3**Sep 2, 2020  
184 days to decisionK200516 · Product code: **OBO** · Ophthalmic  
Source: <https://www.510kdatabase.net/k200516/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Mar 2, 2020
Decision date	Sep 2, 2020
Days to decision	184 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Optomedical Technologies GmbH</b>
Location	Luebeck, DE
Contact	Julia Behrens
510(k) history	2 submissions · 2 cleared · 2015-2020

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Emergo Global Consulting, LLC</b>
Contact	Oliver Eikenberg

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200516/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated June 28, 2026