FDA 510(k) Premarket Notification

K200516 OCT-Camera ID 21101A3

CLEARED

Sep 2, 2020
184 days to decision

K200516 · 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	**Optomedical Technologies GmbH**
Location	Luebeck, DE
Contact	Julia Behrens
510(k) history	2 submissions · 2 cleared · 2015-2020

REGULATORY CONSULTANT

Consulting firm	**Emergo Global Consulting, LLC**
Contact	Oliver Eikenberg

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