

K181682 VISULAS greenMar 6, 2019
253 days to decisionK181682 · Product code: **HQF** · Ophthalmic
Source: <https://www.510kdatabase.net/k181682/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Ophthalmic (HQF)
Date received	Jun 26, 2018
Decision date	Mar 6, 2019
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Carl Zeiss Meditec, AG
Location	Dublin, CA, US
Contact	Christian Munster
Website	http://www.zeiss.com/meditec-ag/en_de/home.html
510(k) history	45 submissions · 44 cleared · 2004-2025

Carl Zeiss Meditec, AG is a global medical device manufacturer specializing in innovative solutions for ophthalmology and microsurgery. The company operates with a manufacturing facility in Dublin, US, and delivers diagnostic and surgical instruments to healthcare professionals worldwide. The company has received FDA 510(k) clearances from total submissions since 2004. Ophthalmic devices represent the dominant category, accounting for 71% of submissions. The latest clearance in 2025 reflects continued regulatory activity and product innovation in this specialized field. C...

REGULATORY CONSULTANT

Consulting firm	Biologics Consulting Group, Inc.
Contact	Lisa Graney

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