

K181444 CLARUSJan 10, 2019
223 days to decisionK181444 · Product code: **QER** · Ophthalmic
Source: <https://www.510kdatabase.net/k181444/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Slit-scanning (QER)
Date received	Jun 1, 2018
Decision date	Jan 10, 2019
Days to decision	223 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Carl Zeiss Meditec, Inc.
Location	San Diego, CA, US
Contact	Saurabh Jamkhindikar
510(k) history	29 submissions · 29 cleared · 1993-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181444/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026