

**K191194 CLARUS**Jun 25, 2019  
53 days to decisionK191194 · Product code: **QER** · Ophthalmic  
Source: <https://www.510kdatabase.net/k191194/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Slit-scanning (QER)
Date received	May 3, 2019
Decision date	Jun 25, 2019
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191194/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 17, 2026