FDA 510(k) Premarket Notification

K181444 CLARUS

CLEARED

Jan 10, 2019
223 days to decision

K181444 · 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