

K183200 iSee (rofluvocon D, rofluvocon E) Daily Wear Orthokeratology Contact LensesJan 9, 2019
51 days to decisionK183200 · Product code: **MUW** · Ophthalmic
Source: <https://www.510kdatabase.net/k183200/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lens, Contact (orthokeratology) (MUW)
Date received	Nov 19, 2018
Decision date	Jan 9, 2019
Days to decision	51 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	C&E GP Specialist, Inc.
Location	San Diego, CA, US
Contact	Steve Wagner
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Eyereg Consulting, Inc.
Contact	Bret Andre

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183200/>; 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 June 28, 2026