

**K182984 MaxiTears Contacts PF**Jul 24, 2019  
268 days to decisionK182984 · Product code: **MRC** · Ophthalmic  
Source: <https://www.510kdatabase.net/k182984/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Products, Contact Lens Care, Rigid Gas Permeable (MRC)
Date received	Oct 29, 2018
Decision date	Jul 24, 2019
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Omnivision AG</b>
Location	Neuhausen Am Rheinfall, CH
Contact	Joachim Kolter
510(k) history	1 submissions · 1 cleared · 2019-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Emergo Global Consulting, LLC</b>
Contact	Oliver Eikenberg

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

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