

K181558 Sofclear Enhance (methafilcon A) Daily Wear Contact Lens, Sofclear Colors (methafilcon A) Daily Wear Contact Lens, Sofclear Comfort (methafilcon A) Daily Wear Contact LensSep 6, 2018
85 days to decisionK181558 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k181558/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Jun 13, 2018
Decision date	Sep 6, 2018
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gelflex Laboratories
Location	Perth, Western, Wa, AU
Contact	David Masel
510(k) history	4 submissions · 4 cleared · 1996-2018

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/k181558/> 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 23, 2026