

K180322 Si-Hy (olifilcon B) color silicone hydrogel soft contact lensApr 20, 2018
74 days to decisionK180322 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k180322/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Feb 5, 2018
Decision date	Apr 20, 2018
Days to decision	74 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Visco Vision, Inc.
Location	New Taipei, Luzhou Dist, TW
Contact	Evan Huang
510(k) history	11 submissions · 11 cleared · 2015-2020

REGULATORY CONSULTANT

Consulting firm	Jens Medical Consulting, Ltd.
Contact	Jennifer Ting

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/k180322/> 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