

**K160344 Si-Hy (olifilcon B) sperical silicone hydrogel soft contact lens, Si-Hy (olifilcon B) multifocal silicone hydrogel soft contact lenses, Si-Hy (olifilcon B) toric silicone hydrogel soft contact lens2/16/2016**May 26, 2016  
108 days to decisionK160344 · Product code: LPL · Ophthalmic  
Source: <https://www.510kdatabase.net/k160344/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Feb 8, 2016
Decision date	May 26, 2016
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160344/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026