

K160938 SynergEyes SiH with Hydra-PEG(petrafocon A hem-larafilcon A) Hybrid Daily Wear Lens

Aug 1, 2016
119 days to decision

K160938 · Product code: **HQD** · Ophthalmic
Source: <https://www.510kdatabase.net/k160938/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lens, Contact (other Material) - Daily (HQD)
Date received	Apr 4, 2016
Decision date	Aug 1, 2016
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synergeyes, Inc.
Location	Rockville, MD, US
Contact	James Kirchner
510(k) history	9 submissions · 9 cleared · 2006-2016

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k160938/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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