

K180819 One Day Flat Pack (hioxifilcon A) Daily Disposable Soft Contact LensMay 16, 2018
48 days to decisionK180819 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k180819/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Mar 29, 2018
Decision date	May 16, 2018
Days to decision	48 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Menicon Co, Ltd.
Location	Washington, DC, US
Contact	Kenichi Tanaka
510(k) history	17 submissions · 17 cleared · 1994-2020

REGULATORY CONSULTANT

Consulting firm	Foresight Regulatory Strategies, Inc.
Contact	Ellen M. Beucler

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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