

**K180004 Menicon ASRB (asmofilcon A) Silicone Hydrogel Soft Contact Lens**Feb 22, 2018  
51 days to decisionK180004 · Product code: LPL · Ophthalmic  
Source: <https://www.510kdatabase.net/k180004/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Jan 2, 2018
Decision date	Feb 22, 2018
Days to decision	51 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Foresight Regulatory Strategies, Inc.</b>
Contact	Ellen M. Beucler

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180004/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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