

**K191121 Apioc (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens, Apioc P for Presbyopia (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens, Apioc A for Astigmatism (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens, Apioc AP (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens**

Sep 6, 2019  
133 days to decision

K191121 · Product code: LPL · Ophthalmic  
Source: <https://www.510kdatabase.net/k191121/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Apr 26, 2019
Decision date	Sep 6, 2019
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lentechs, LLC</b>
Location	Columbus, OH, US
Contact	Robin Sears
510(k) history	1 submissions · 1 cleared · 2019-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Eyereg Consulting, Inc.</b>
Contact	Bret Andre

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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