

# K240918 Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens with UV Blocking for Myopia and Hyperopia

Oct 25, 2024  
205 days to decision

K240918 · Product code: LPL · Ophthalmic  
Source: <https://www.510kdatabase.net/k240918/>

## SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Apr 3, 2024
Decision date	Oct 25, 2024
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens with UV Blocking for Astigmatism

## APPLICANT

Company	<b>Bruno Vision Care, LLC</b>
Location	Boca Raton, FL, US
Contact	Eddie Catalfamo
510(k) history	2 submissions · 2 cleared · 2024-2025

## REGULATORY CONSULTANT

Consulting firm	<b>Covington &amp; Burling, Llp</b>
Contact	Christina Kuhn

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

## CLINICAL EVIDENCE - NCT05927753

### Study to Evaluate the Clinical Performance of Deseyne (Vifilcon C) Daily Disposable Soft Contact Lens

Status	Completed
Enrollment	81 patients (actual)
Study sites	3 sites
Condition studied	Refractive Error - Myopia Bilateral
Primary purpose	Other
Study type	Interventional
Study design	Parallel
Masking	Open label
Completion date	Jan 8, 2024
Sponsor	Bruno Vision Care (Industry)

#### Primary outcome

Change From Baseline to Each Post-Baseline Visit in Distance logMAR Visual Acuity (Letters Read) by Eye

#### Secondary outcome

#### Symptoms/Complaints

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT05927753](https://clinicaltrials.gov/study/NCT05927753)

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k240918/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)), ClinicalTrials.gov (U.S. National Library of Medicine).  
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