

**K230372 VitreJect Syringe**Sep 8, 2023  
207 days to decisionK230372 · Product code: **QLY** · General Hospital  
Source: <https://www.510kdatabase.net/k230372/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmic Syringe (QLY)
Date received	Feb 13, 2023
Decision date	Sep 8, 2023
Days to decision	207 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ocuject, LLC</b>
Location	Newport Beach, CA, US
Contact	Leonid Lerner
510(k) history	8 submissions · 8 cleared · 2017-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Namsa</b>
Contact	Heidi Busz

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/k230372/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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