

**K243322 Altaviz Intravitreal Syringe**May 9, 2025  
198 days to decisionK243322 · Product code: **QLY** · General Hospital  
Source: <https://www.510kdatabase.net/k243322/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmic Syringe (QLY)
Date received	Oct 23, 2024
Decision date	May 9, 2025
Days to decision	198 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Altaviz, LLC</b>
Location	Irvine, CA, US
Contact	James Lescoulie
510(k) history	3 submissions · 3 cleared · 2022-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Allied Regulatory Consulting</b>
Contact	Sean Griffin

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/k243322/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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