FDA 510(k) Premarket Notification

K243322 Altaviz Intravitreal Syringe

CLEARED

May 9, 2025
198 days to decision

K243322 · Product code: **QLY** · General Hospital
Source: https://www.510kdatabase.net/k243322/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Allied Regulatory Consulting**
Contact	Sean Griffin

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