

K231261 Altaviz Needle Kit IIJul 27, 2023
87 days to decisionK231261 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k231261/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	May 1, 2023
Decision date	Jul 27, 2023
Days to decision	87 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](https://accessdata.fda.gov)

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