FDA 510(k) Premarket Notification

K222681 Altaviz Needle Kit

CLEARED

Dec 5, 2022
90 days to decision

K222681 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k222681/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 6, 2022
Decision date	Dec 5, 2022
Days to decision	90 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