

K251715 FlowArt® Vial Access Device VentedOct 14, 2025
132 days to decision

K251715 · Product code: LHI · General Hospital

Source: <https://www.510kdatabase.net/k251715/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, I.v. Fluid Transfer (LHI)
Date received	Jun 4, 2025
Decision date	Oct 14, 2025
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Asset Medikal
Location	Istanbul, TR
Contact	Ebru Sirali
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Arazy Group Consultants, Inc.
Contact	Raymond Kelly

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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