

K231071 Mix2Vial® Transfer DeviceJan 19, 2024
280 days to decision

K231071 · Product code: LHI · General Hospital

Source: <https://www.510kdatabase.net/k231071/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, I.v. Fluid Transfer (LHI)
Date received	Apr 14, 2023
Decision date	Jan 19, 2024
Days to decision	280 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	West Pharma Services II, Ltd.
Location	Ra'Anana, IL
Contact	Ilanit Goldgraber
510(k) history	5 submissions · 5 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	West Pharmaceutical Services, Inc.
Contact	Lauren Tiller

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231071/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026