FDA 510(k) Premarket Notification

K231071 Mix2Vial® Transfer Device

CLEARED

Jan 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 Il, 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