FDA 510(k) Premarket Notification

K230464 MixJect® Transfer Device

CLEARED

May 22, 2023
90 days to decision

K230464 · Product code: **LHI** · General Hospital
Source: https://www.510kdatabase.net/k230464/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, I.v. Fluid Transfer (LHI)
Date received	Feb 21, 2023
Decision date	May 22, 2023
Days to decision	90 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	Llanit Goldgraber
510(k) history	5 submissions · 5 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	**West Pharmaceutical Services, Inc.**
Contact	Fred Cowdery

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov