

**K230464 MixJect® Transfer Device**May 22, 2023  
90 days to decision

K230464 · Product code: LHI · General Hospital

Source: <https://www.510kdatabase.net/k230464/>**SUBMISSION DETAILS**

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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**

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Company	<b>West Pharma Services II, Ltd.</b>
Location	Ra&apos;Anana, IL
Contact	Llanit Goldgraber
510(k) history	5 submissions · 5 cleared · 2022-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>West Pharmaceutical Services, Inc.</b>
Contact	Fred Cowdery

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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