

K230988 Vial2Bag Advanced® 13mm Admixture DeviceDec 1, 2023
239 days to decisionK230988 · Product code: LHI · General Hospital
Source: <https://www.510kdatabase.net/k230988/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, I.v. Fluid Transfer (LHI)
Date received	Apr 6, 2023
Decision date	Dec 1, 2023
Days to decision	239 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	Lynn Lundy

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230988/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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