FDA 510(k) Premarket Notification

K251139 KabiHelp® Uno

CLEARED

Jan 9, 2026
270 days to decision

K251139 · Product code: **KPE** · General Hospital
Source: https://www.510kdatabase.net/k251139/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Container, I.v. (KPE)
Date received	Apr 14, 2025
Decision date	Jan 9, 2026
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	KabiHelp® Advance plus

APPLICANT

Company	**Fresenius Kabi AG**
Location	Lake Zurich, IL, US
Contact	Rhoda Lynn Valera
Website	http://www.fresenius-kabi.com/
510(k) history	12 submissions · 12 cleared · 2013-2026

Fresenius Kabi AG is a global healthcare company specializing in infusion therapy, IV drugs, and medical devices. The company operates with a manufacturing facility in Lake Zurich, Illinois, and serves hospitals and healthcare systems worldwide. Fresenius Kabi has received FDA 510(k) clearances from total submissions since 2013. The company's regulatory portfolio focuses on infusion systems, administration sets, and blood processing technologies for general hospital and cardiovascular applications. The latest clearance in 2026 demonstrates continued innovation and active ...

REGULATORY CONSULTANT

Consulting firm	**Fresenius Kabi**
Contact	Rhoda Lynn Valera

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