FDA 510(k) Premarket Notification

CLEARED

K210073 Agilia VP Infusion System, Agilia VP MC WIFI Infusion Pump, Volumat Lines Administration Sets, Agilia Link, Agilia Duo

Mar 1, 2022
413 days to decision

K210073 · Product code: **FRN** · General Hospital
Source: https://www.510kdatabase.net/k210073/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Jan 12, 2021
Decision date	Mar 1, 2022
Days to decision	413 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fresenius Kabi AG**
Location	Lake Zurich, IL, US
Contact	Keith Dunn
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, LLC, USA**
Contact	Keith Dunn

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