

**K220301 Volumat Line**Jun 2, 2023  
485 days to decisionK220301 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k220301/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Feb 2, 2022
Decision date	Jun 2, 2023
Days to decision	485 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Fresenius Kabi</b>
Location	Bad Hersfeld, DE
Contact	Keith Dunn
Website	<a href="http://www.fresenius-kabi.com/">http://www.fresenius-kabi.com/</a>
510(k) history	2 submissions · 2 cleared · 2023-2023

Fresenius Kabi is a global healthcare company specializing in pharmaceutical, nutritional, and medical technology solutions. The company operates with a manufacturing facility in Bad Hersfeld, Germany, and maintains a worldwide presence across multiple regions. Fresenius Kabi has received FDA 510(k) clearances from total submissions. The company's regulatory focus centers on General Hospital devices, with clearances granted in 2023. This represents a historical record of FDA submissions in the medical device space. The company's cleared devices include intravenous adminis...

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Fresenius Kabi, LLC, USA</b>
Contact	Keith Dunn

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

---