

**K201936 SmartSite Bag 500mL, SmartSite Bag 250 mL,
SmartSite Bag 100 mL**May 6, 2021
297 days to decisionK201936 · Product code: **KPE** · General Hospital
Source: <https://www.510kdatabase.net/k201936/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Container, I.v. (KPE)
Date received	Jul 13, 2020
Decision date	May 6, 2021
Days to decision	297 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gilero, LLC
Location	Morrisville, NC, US
Contact	Kristin Benokraitis
510(k) history	2 submissions · 2 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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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