FDA 510(k) Premarket Notification

K243486 SmartSiteTM Vented Vial Access Device

CLEARED

Dec 6, 2024
28 days to decision

K243486 · Product code: **LHI** · General Hospital
Source: https://www.510kdatabase.net/k243486/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, I.v. Fluid Transfer (LHI)
Date received	Nov 8, 2024
Decision date	Dec 6, 2024
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Yukon Medical, LLC**
Location	Durham, NC, US
Contact	Todd Korogi
Website	https://yukonmedical.com
510(k) history	8 submissions · 8 cleared · 2012-2025

Yukon Medical, LLC is a developer of pharmaceutical preparation and drug delivery devices headquartered in Durham, North Carolina. Founded in 2008, the company designs innovative solutions for safe medication preparation and administration in clinical settings. Yukon Medical has received FDA 510(k) clearances from total submissions since 2012. All submissions focus on General Hospital devices. The company's latest clearance was in 2025, demonstrating continued regulatory activity and product innovation. The company specializes in vial access devices and closed system tran...

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