

K151963 SmartSite Vented Vial Access DeviceJul 31, 2015
15 days to decisionK151963 · Product code: LHI · General Hospital
Source: <https://www.510kdatabase.net/k151963/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, I.v. Fluid Transfer (LHI)
Date received	Jul 16, 2015
Decision date	Jul 31, 2015
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Yukon Medical, LLC
Location	Durham, NC, US
Contact	CARL DUPPER
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...
