

**K132863 SMARTSITE VIALSHIELD**Oct 4, 2013  
22 days to decisionK132863 · Product code: LHI · General Hospital  
Source: <https://www.510kdatabase.net/k132863/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, I.v. Fluid Transfer (LHI)
Date received	Sep 12, 2013
Decision date	Oct 4, 2013
Days to decision	22 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Yukon Medical, LLC</b>
Location	Durham, NC, US
Website	<a href="https://yukonmedical.com">https://yukonmedical.com</a>
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...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k132863/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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