

K240761 Arisure® Closed Male Luer with Spike Adapter (YM060)Mar 21, 2025
366 days to decisionK240761 · Product code: LHI · General Hospital
Source: <https://www.510kdatabase.net/k240761/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Set, I.v. Fluid Transfer (LHI) |
| Date received | Mar 20, 2024 |
| Decision date | Mar 21, 2025 |
| Days to decision | 366 days |
| Third-party review | No |
| 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...