

**K201422 Arisure Closed System Drug Transfer Device (CSTD)**Mar 2, 2021  
277 days to decisionK201422 · Product code: **ONB** · General Hospital  
Source: <https://www.510kdatabase.net/k201422/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System (ONB)
Date received	May 29, 2020
Decision date	Mar 2, 2021
Days to decision	277 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Yukon Medical, LLC</b>
Location	Durham, NC, US
Contact	Pamela McNulty
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...