

**K241353 PowerLoc™ Max Power Injectable Infusion Set**Nov 27, 2024  
198 days to decisionK241353 · Product code: **PTI** · General HospitalSource: <https://www.510kdatabase.net/k241353/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-coring (huber) Needle (PTI)
Date received	May 13, 2024
Decision date	Nov 27, 2024
Days to decision	198 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	SafeStep™ Huber Needle Set

**APPLICANT**

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Company	<b>Bard Access Systems, Inc.</b>
Location	Salt Lake City, UT, US
Contact	Catherine Langford
510(k) history	21 submissions · 20 cleared · 1993-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241353/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026