

**K182819 Decanting Device**Dec 2, 2019  
424 days to decisionK182819 · Product code: **LHI** · General Hospital  
Source: <https://www.510kdatabase.net/k182819/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, I.v. Fluid Transfer (LHI)
Date received	Oct 4, 2018
Decision date	Dec 2, 2019
Days to decision	424 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gcmedica Enterprise Ltd.(Wuxi)</b>
Location	Wuxi, CN
Contact	Mona Zhang
510(k) history	2 submissions · 2 cleared · 2019-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182819/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026