

**K973654 VIAL-MATE RECONSTITUTION DEVICE (2B8071)**Oct 24, 1997  
29 days to decisionK973654 · Product code: LHI · General Hospital  
Source: <https://www.510kdatabase.net/k973654/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, I.v. Fluid Transfer (LHI)
Date received	Sep 25, 1997
Decision date	Oct 24, 1997
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Baxter Healthcare Corp</b>
Location	Mchenry, IL, US
Contact	TAMIMA ITANI
510(k) history	505 submissions · 496 cleared · 1977-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973654/> 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 17, 2026