

**K864395 LOW VOLUME EXTENSION SET**Dec 16, 1986  
40 days to decisionK864395 · Product code: **FPK** · General HospitalSource: <https://www.510kdatabase.net/k864395/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubing, Fluid Delivery (FPK)
Date received	Nov 6, 1986
Decision date	Dec 16, 1986
Days to decision	40 days
Third-party review	No

**APPLICANT**

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Company	<b>Panamedix, Inc.</b>
Location	Costa Mesa, CA, US
Contact	CARL JOHNSTON
510(k) history	6 submissions · 6 cleared · 1986-1988

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k864395/>; 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 July 3, 2026