

**K950766 SIGMA 8000 AND SIGMA 8002**Mar 22, 1995  
33 days to decisionK950766 · Product code: **FRN** · General Hospital  
Source: <https://www.510kdatabase.net/k950766/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Feb 17, 1995
Decision date	Mar 22, 1995
Days to decision	33 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sigma Intl. General Medical Apparatus, Inc.</b>
Location	Medina, NY, US
Contact	CHARLES L MARTINA
510(k) history	1 submissions · 1 cleared · 1995-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k950766/> 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 6, 2026