

**K820038 SIGMA 7000**Jan 26, 1983  
19 days to decisionK820038 · Product code: **FRN** · General Hospital  
Source: <https://www.510kdatabase.net/k820038/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Jan 7, 1983
Decision date	Jan 26, 1983
Days to decision	19 days
Third-party review	No

**APPLICANT**

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Company	<b>Sigma</b>
Location	MD, US
Website	<a href="http://www.sigmafotbal.cz/">http://www.sigmafotbal.cz/</a>
510(k) history	6 submissions · 6 cleared · 1983-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k820038/>; 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 June 29, 2026