

**K821139 SPS-SINGLE PATIENT SYSTEM**May 10, 1982  
19 days to decisionK821139 · Product code: **FIR** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k821139/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Extra-luminal (FIR)
Date received	Apr 21, 1982
Decision date	May 10, 1982
Days to decision	19 days
Third-party review	No

**APPLICANT**

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Company	<b>Extracorporeal Medical Specialities, Inc.</b>
Location	Mchenry, IL, US
Contact	JAMES K MCCRACKEN
510(k) history	69 submissions · 69 cleared · 1976-1984

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k821139/>; 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 28, 2026