

**K970700 FRESENIUS POLYSULFONE HEMODIALYZERS, BOTH  
LOW AND HIGH FLUX**Sep 15, 1998  
567 days to decisionK970700 · Product code: **MSE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k970700/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemodialyzer, Re-use, Low Flux (MSE)
Date received	Feb 25, 1997
Decision date	Sep 15, 1998
Days to decision	567 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Fresenius USA, Inc.</b>
Location	Walker, MI, US
Contact	TOM FOLDEN
510(k) history	38 submissions · 37 cleared · 1984-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970700/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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