

**K970648 PRIMUS HOLLOW FIBER DIALYZER (MODELS
1000,1000S,1350,1350S,2000,2000S)**Jan 5, 1998
319 days to decisionK970648 · Product code: **MSF** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k970648/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemodialyzer, Re-use, High Flux (MSF)
Date received	Feb 20, 1997
Decision date	Jan 5, 1998
Days to decision	319 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Renal Systems, Inc.
Location	Mchenry, IL, US
Contact	LYNN M LUEDERS
510(k) history	35 submissions · 35 cleared · 1977-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970648/>; Data sourced from FDA 510(k) public records (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. - Generated June 29, 2026