

**K012510 MODIFICATION TO: LIFEMATE HEMOFILTRATION SYSTEM**Oct 19, 2001  
74 days to decisionK012510 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k012510/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Aug 6, 2001
Decision date	Oct 19, 2001
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nxstage Medical, Inc.</b>
Location	Tewksburt, MA, US
Contact	KAREN ST.ONGE
510(k) history	51 submissions · 51 cleared · 2001-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012510/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 1, 2026