

**K021060 FRESENIUS ICARE MONITORING SYSTEM**Nov 13, 2002  
225 days to decisionK021060 · Product code: **FKP** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k021060/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Dialysate Delivery, Single Patient (FKP)
Date received	Apr 2, 2002
Decision date	Nov 13, 2002
Days to decision	225 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fresenius Medical Care North America</b>
Location	Lexington, MA, US
Contact	NICHOLE RIEK
510(k) history	43 submissions · 43 cleared · 1998-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k021060/> 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 28, 2026