

**K083542 FRESENIUS STERILE STAY SAFE CAP**Dec 29, 2008  
31 days to decisionK083542 · Product code: **KDJ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k083542/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, For Peritoneal Dialysis, Disposable (KDJ)
Date received	Nov 28, 2008
Decision date	Dec 29, 2008
Days to decision	31 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	JANET KAY
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/k083542/> 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 23, 2026