

K250404 stay•safe® catheter extension set with Safe- Lock, 12 inch

Apr 3, 2025
50 days to decisionK250404 · Product code: **KDJ** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k250404/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Set, Administration, For Peritoneal Dialysis, Disposable (KDJ) |
| Date received | Feb 12, 2025 |
| Decision date | Apr 3, 2025 |
| Days to decision | 50 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | stay•safe® catheter extension set with Luer-Lock, 6 inch; stay•safe® catheter extension set with Luer-Lock, 12 inch; stay•safe® catheter extension set with Luer-Lock, 18 inch; stay•safe® to Luer-Lock Adapter, 4 inch |

APPLICANT

| | |
|----------------|---|
| Company | Fresenius Medical Care Renal Therapies Group, LLC |
| Location | Waltham, MA, US |
| Contact | Caitlin Kalda |
| Website | https://www.freseniusmedicalcare.com |
| 510(k) history | 50 submissions · 50 cleared · 2013-2026 |

Fresenius Medical Care Renal Therapies Group, LLC is a medical device manufacturer based in Waltham, US. The company specializes in renal therapy and dialysis technologies. The company has received FDA 510(k) clearances from total submissions since 2013. 96% of submissions focus on Gastroenterology & Urology devices, reflecting the company's core expertise in dialysis and renal replacement therapies. The latest clearance was in 2026, confirming active regulatory engagement. Recent cleared devices include hemodialysis systems, dialyzers, body composition monitors, and dial...