

K222318 Fresenius Liberty Select CyclorOct 31, 2022
90 days to decisionK222318 · Product code: **FKX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k222318/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Peritoneal, Automatic Delivery (FKX) |
| Date received | Aug 2, 2022 |
| Decision date | Oct 31, 2022 |
| Days to decision | 90 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Fresenius Medical Care Renal Therapies Group, LLC |
| Location | Waltham, MA, US |
| Contact | Denise Oppermann |
| 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...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k222318/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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