

K181108 Fresenius Liberty Select CyclorMay 24, 2018
27 days to decisionK181108 · Product code: **FKX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k181108/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | System, Peritoneal, Automatic Delivery (FKX) |
| Date received | Apr 27, 2018 |
| Decision date | May 24, 2018 |
| Days to decision | 27 days |
| Third-party review | 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...

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