

**K070222 FRESENIUS RENAL ACUTE CARE (RAC 100) FILTER,
MODEL 0500610N**Apr 24, 2007
90 days to decisionK070222 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k070222/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI) |
| Date received | Jan 24, 2007 |
| Decision date | Apr 24, 2007 |
| Days to decision | 90 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Fresenius Medical Care North America |
| Location | Lexington, MA, US |
| Contact | JANET C KAY |
| 510(k) history | 43 submissions · 43 cleared · 1998-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k070222/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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