

**K861916 ADVANCED PERFORMANCE HOLLOW FIBER
DIALYZER**Jul 10, 1986
52 days to decisionK861916 · Product code: **FJI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k861916/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dialyzer, Capillary, Hollow Fiber (FJI) |
| Date received | May 19, 1986 |
| Decision date | Jul 10, 1986 |
| Days to decision | 52 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | National Medical Care, Medical Products Div., Inc. |
| Location | Rockleigh, NJ, US |
| Contact | DEL DONNA |
| 510(k) history | 62 submissions · 62 cleared · 1985-1996 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k861916/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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