

K890111 GAMBRO ALWALL GFE 8 & 9 HOLLOW FIBER DIALYZERFeb 8, 1989
28 days to decisionK890111 · Product code: **FJI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k890111/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dialyzer, Capillary, Hollow Fiber (FJI) |
| Date received | Jan 11, 1989 |
| Decision date | Feb 8, 1989 |
| Days to decision | 28 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Gambro, Inc. |
| Location | Mchenry, IL, US |
| Contact | JEFFREY SHIDEMAN,PHD |
| 510(k) history | 86 submissions · 86 cleared · 1976-2009 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k890111/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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