

K854575 MODIFIED AM-SERIES DIALYZERSDec 2, 1985
26 days to decisionK854575 · Product code: **FJI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k854575/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dialyzer, Capillary, Hollow Fiber (FJI) |
| Date received | Nov 6, 1985 |
| Decision date | Dec 2, 1985 |
| Days to decision | 26 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Asahi Medical Co., Ltd. |
| Location | Walker, MI, US |
| Contact | RICHARD T NEY |
| 510(k) history | 16 submissions · 16 cleared · 1983-2004 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k854575/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 30, 2026