

K823288 AMICON DIAFILTERS 20 & 30 HEMOFILTERSDec 16, 1982
42 days to decisionK823288 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k823288/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI) |
| Date received | Nov 4, 1982 |
| Decision date | Dec 16, 1982 |
| Days to decision | 42 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Amicon, Inc. |
| Location | Mchenry, IL, US |
| 510(k) history | 20 submissions · 20 cleared · 1976-1993 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k823288/> 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 May 14, 2026