

K910236 RENAFLO HDF 1350 HEMODIAFILTERApr 9, 1991
81 days to decisionK910236 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k910236/>**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 | Jan 18, 1991 |
| Decision date | Apr 9, 1991 |
| Days to decision | 81 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Minntech Corp. |
| Location | Minneapolis, MN, US |
| Contact | LEROY J FISCHBACH |
| 510(k) history | 33 submissions · 33 cleared · 1987-2012 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k910236/>; 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 13, 2026