FDA 510(k) Premarket Notification

# K910236 RENAFLO HDF 1350 HEMODIAFILTER

**CLEARED**

Apr 9, 1991
81 days to decision

K910236 · Product code: **KDI** · Gastroenterology & Urology
Source: 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 |