# K953996 NIKKISO CO, LTD., FLX10GW, 12GW, 15GW, 18GW & 21GW HEMODIALYZERS

**CLEARED**

Mar 19, 1997
573 days to decision

K953996 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k953996/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI) |
| Date received | Aug 24, 1995 |
| Decision date | Mar 19, 1997 |
| Days to decision | 573 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **NIKKISO CO., LTD.** |
| Location | Mchenry, IL, US |
| Contact | JEFFERY R SHIDERMAN |
| 510(k) history | 11 submissions · 11 cleared · 1981-2025 |