FDA 510(k) Premarket Notification

# K081313 SH14 HEMOCONCENTRATOR

**CLEARED**

Nov 19, 2008
194 days to decision

K081313 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k081313/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI) |
| Date received | May 9, 2008 |
| Decision date | Nov 19, 2008 |
| Days to decision | 194 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Sorin Group Italia S.R.L.** |
| Location | Mirandola, IT |
| Contact | BARRY SALL |
| 510(k) history | 61 submissions · 61 cleared · 1995-2026 |