

K081313 SH14 HEMOCONCENTRATORNov 19, 2008
194 days to decisionK081313 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081313/> 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 24, 2026