

K243264 DHF 0.2 Hemoconcentrator (DHF 02)Apr 25, 2025
192 days to decisionK243264 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k243264/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Oct 15, 2024
Decision date	Apr 25, 2025
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	DHF 0.6 Hemoconcentrator (DHF 06); SH 14 Hemoconcentrator (SH 14)

APPLICANT

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

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