FDA 510(k) Premarket Notification

K250508 AK 98 Dialysis Machine (955607)

CLEARED

Aug 1, 2025
161 days to decision

K250508 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k250508/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Feb 21, 2025
Decision date	Aug 1, 2025
Days to decision	161 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vantive US Healthcare, LLC**
Location	Deerfield Lake, IL, US
Contact	Kristen Bozzelli
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k250508/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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