FDA 510(k) Premarket Notification

CLEARED

K243237 2008T HD SYS. CDX BLUESTAR (191124)

Jun 13, 2025
246 days to decision

K243237 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k243237/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Oct 10, 2024
Decision date	Jun 13, 2025
Days to decision	246 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	2008T HD SYS. CDX W/bibag BLUESTAR (191126); 2008T HD SYS. W/O CDX BLUESTAR (191128); 2008T HD SYS. W/O CDX W/bibag BLUESTAR (191130)

APPLICANT

Company	**Fresenius Medical Care Renal Therapies Group, LLC**
Location	Waltham, MA, US
Contact	Tara Kenney
Website	https://www.freseniusmedicalcare.com
510(k) history	50 submissions · 50 cleared · 2013-2026

Fresenius Medical Care Renal Therapies Group, LLC is a medical device manufacturer based in Waltham, US. The company specializes in renal therapy and dialysis technologies. The company has received FDA 510(k) clearances from total submissions since 2013. 96% of submissions focus on Gastroenterology & Urology devices, reflecting the company's core expertise in dialysis and renal replacement therapies. The latest clearance was in 2026, confirming active regulatory engagement. Recent cleared devices include hemodialysis systems, dialyzers, body composition monitors, and dial...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k243237/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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