

K080964 FRESENIUS MODEL 2008T HEMODIALYSIS MACHINEJan 14, 2009
285 days to decisionK080964 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k080964/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Apr 4, 2008
Decision date	Jan 14, 2009
Days to decision	285 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fresenius Medical Care North America
Location	Lexington, MA, US
Contact	JANET C KAY
510(k) history	43 submissions · 43 cleared · 1998-2025

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