

K083778 XENIUM XPH, MODELS 110, 130, 150, 170, 190 AND 210Feb 20, 2009
63 days to decisionK083778 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k083778/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Dec 19, 2008
Decision date	Feb 20, 2009
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Baxter Healthcare Corporation
Location	Round Lake, IL, US
Contact	DIANE RENNPFERD
510(k) history	61 submissions · 60 cleared · 2004-2025

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