

K171671 Prismaflex System 8.10Feb 23, 2018
262 days to decisionK171671 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k171671/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jun 6, 2017
Decision date	Feb 23, 2018
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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