

K213639 Revaclear 500, Revaclear 400, Revaclear 300Jan 24, 2022
67 days to decisionK213639 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k213639/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Nov 18, 2021
Decision date	Jan 24, 2022
Days to decision	67 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Gambro Dasco Spa
Contact	Alberto Pancanti

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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