FDA 510(k) Premarket Notification

CLEARED

K212216 Prismaflex ST60 Set, Prismaflex ST100 Set, Prismaflex ST150 set

Apr 1, 2022
259 days to decision

K212216 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k212216/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jul 16, 2021
Decision date	Apr 1, 2022
Days to decision	259 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	Fortunato (Tito) Aldape
510(k) history	61 submissions · 60 cleared · 2004-2025

REGULATORY CONSULTANT

Consulting firm	**Gambro Industries**
Contact	Maud Humbert

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