FDA 510(k) Premarket Notification

K193482 PrisMax System Version 3

CLEARED

Mar 13, 2020
87 days to decision

K193482 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k193482/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Dec 17, 2019
Decision date	Mar 13, 2020
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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