FDA 510(k) Premarket Notification

K190910 PrisMax System Version 2

CLEARED

Jul 25, 2019
108 days to decision

K190910 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k190910/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Apr 8, 2019
Decision date	Jul 25, 2019
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Baxter Healthcare Corp**
Location	Mchenry, IL, US
Contact	Chris Scavotto
510(k) history	505 submissions · 496 cleared · 1977-2019

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k190910/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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