FDA 510(k) Premarket Notification

K030975 EXELTRA PLUS HIGH FLUX DIALYZER, MODEL 210

CLEARED

Apr 25, 2003
28 days to decision

K030975 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k030975/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Mar 28, 2003
Decision date	Apr 25, 2003
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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