FDA 510(k) Premarket Notification

CLEARED

K974652 BLOOD MONITOR PUMP WITH ULTRAFILTRATION CONTROLLER

Jul 10, 1998
210 days to decision

K974652 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k974652/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Dec 12, 1997
Decision date	Jul 10, 1998
Days to decision	210 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