FDA 510(k) Premarket Notification

CLEARED

K201809 AK 98 Dialysis Machine, U9000 Ultrafilter, C705 Expansion Chamber Accessory

Mar 10, 2021
252 days to decision

K201809 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k201809/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jul 1, 2020
Decision date	Mar 10, 2021
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Baxter Healthcare Corportation**
Location	Round Lake, IL, US
Contact	Kristen Bozzelli
510(k) history	3 submissions · 3 cleared · 2020-2024