FDA 510(k) Premarket Notification

K023874 SYSTEM 100 ULTRAFILTRATION CATHETER

CLEARED

Nov 20, 2003
364 days to decision

K023874 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k023874/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Nov 21, 2002
Decision date	Nov 20, 2003
Days to decision	364 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Chf Solutions, Inc.**
Location	Washington, DC, US
Contact	AMY PETERSON
510(k) history	13 submissions · 13 cleared · 2002-2020