FDA 510(k) Premarket Notification

K024124 SYSTEM 100-UF 500 CIRCUIT WITH IN-LINE NEEDLELESS ACCESS PORT

CLEARED

Mar 14, 2003
88 days to decision

K024124 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k024124/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Dec 16, 2002
Decision date	Mar 14, 2003
Days to decision	88 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