FDA 510(k) Premarket Notification

K801826 RENAFLO HOLLOW FIBER DIALYZERS #MP 140

CLEARED

Sep 26, 1980
57 days to decision

K801826 · Product code: **FJI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k801826/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	Jul 31, 1980
Decision date	Sep 26, 1980
Days to decision	57 days
Third-party review	No

APPLICANT

Company	**Renal Systems, Inc.**
Location	Mchenry, IL, US
510(k) history	35 submissions · 35 cleared · 1977-1998