FDA 510(k) Premarket Notification

K801559 HOLLO FIBER DIALYZER

CLEARED

Oct 31, 1980
115 days to decision

K801559 · Product code: **FJI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k801559/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	Jul 8, 1980
Decision date	Oct 31, 1980
Days to decision	115 days
Third-party review	No

APPLICANT

Company	**Renal Devices, Inc.**
Location	Mchenry, IL, US
510(k) history	4 submissions · 4 cleared · 1979-1981