FDA 510(k) Premarket Notification

K802122 CLIRANS TH13 HOLLOW FIBER DIALYZER

CLEARED

Dec 18, 1980
105 days to decision

K802122 · Product code: **FJI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k802122/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	Sep 4, 1980
Decision date	Dec 18, 1980
Days to decision	105 days
Third-party review	No

APPLICANT

Company	**Terumo America, Inc.**
Location	Mchenry, IL, US
510(k) history	31 submissions · 31 cleared · 1976-1981