FDA 510(k) Premarket Notification

K772362 AVF SET FOR SINGLE NEEDLE HEMODIALYSIS

CLEARED

Mar 17, 1978
80 days to decision

K772362 · Product code: **FIE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k772362/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Dec 27, 1977
Decision date	Mar 17, 1978
Days to decision	80 days
Third-party review	No

APPLICANT

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