FDA 510(k) Premarket Notification

K771206 AV FISTULA NEEDLE SET

CLEARED

Jul 15, 1977
10 days to decision

K771206 · Product code: **FIE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k771206/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Jul 5, 1977
Decision date	Jul 15, 1977
Days to decision	10 days
Third-party review	No

APPLICANT

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