FDA 510(k) Premarket Notification

K891062 TERUMO AV FISTULA NEEDLE SET

CLEARED

Jun 22, 1989
113 days to decision

K891062 · Product code: **FIE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k891062/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Mar 1, 1989
Decision date	Jun 22, 1989
Days to decision	113 days
Third-party review	No

APPLICANT

Company	**Terumo Medical Corp.**
Location	Elkton, MD, US
Contact	GEORGE S MOMODA
510(k) history	143 submissions · 143 cleared · 1980-2011