FDA 510(k) Premarket Notification

K811838 MEDISYSTEMS FISTULA NEEDLE

CLEARED

Sep 8, 1981
69 days to decision

K811838 · Product code: **FIE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k811838/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Jul 1, 1981
Decision date	Sep 8, 1981
Days to decision	69 days
Third-party review	No

APPLICANT

Company	**Medisystems Corp.**
Location	Mchenry, IL, US
510(k) history	22 submissions · 22 cleared · 1981-2007