FDA 510(k) Premarket Notification

K812566 UNIVERSAL SUTURE PASSER

CLEARED

Nov 10, 1981
62 days to decision

K812566 · Product code: **GDL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k812566/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Suturing, Reusable (GDL)
Date received	Sep 9, 1981
Decision date	Nov 10, 1981
Days to decision	62 days
Third-party review	No

APPLICANT

Company	**Ortho Pared Instruments, Inc.**
Location	Mchenry, IL, US
510(k) history	4 submissions · 4 cleared · 1981-1983