FDA 510(k) Premarket Notification

K813286 PRE-PACK TENS

CLEARED

Jan 22, 1982
60 days to decision

K813286 · Product code: **GDY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k813286/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauze/sponge, Internal, X-ray Detectable (GDY)
Date received	Nov 23, 1981
Decision date	Jan 22, 1982
Days to decision	60 days
Third-party review	No

APPLICANT

Company	**Cunningham Woodland, Inc.**
Location	Mchenry, IL, US
510(k) history	10 submissions · 10 cleared · 1981-1983