FDA 510(k) Premarket Notification

K823671 NO-GAUZE LAPAROTOMY SPONGE

CLEARED

Jan 9, 1983
33 days to decision

K823671 · Product code: **GDY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k823671/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauze/sponge, Internal, X-ray Detectable (GDY)
Date received	Dec 7, 1982
Decision date	Jan 9, 1983
Days to decision	33 days
Third-party review	No

APPLICANT

Company	**Surgilite Intl., Inc.**
Location	Mchenry, IL, US
510(k) history	5 submissions · 5 cleared · 1977-1983