FDA 510(k) Premarket Notification

K812391 NEUROSPONGES

CLEARED

Nov 24, 1981
96 days to decision

K812391 · Product code: **GDY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k812391/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauze/sponge, Internal, X-ray Detectable (GDY)
Date received	Aug 20, 1981
Decision date	Nov 24, 1981
Days to decision	96 days
Third-party review	No

APPLICANT

Company	**Winn Hirsch & Assoc.**
Location	Mchenry, IL, US
510(k) history	11 submissions · 10 cleared · 1976-1988