FDA 510(k) Premarket Notification

K984262 MODIFICATION OF BIONECT HYDROGEL GAUZE PADS

CLEARED

Feb 10, 1999
85 days to decision

K984262 · Product code: **MGQ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k984262/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound And Burn, Hydrogel W/drug And/or Biologic (MGQ)
Date received	Nov 17, 1998
Decision date	Feb 10, 1999
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Fidia Pharmaceutical Corp.**
Location	Washington, DC, US
Contact	ROBERTO FIORENTINI
510(k) history	10 submissions · 9 cleared · 1997-1999