

K984413 BIONECT HYDROGELFeb 10, 1999
85 days to decisionK984413 · Product code: **MGQ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k984413/>**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

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