

K984266 MODIFICATION OF BIONECT HYDROGEL SPRAYFeb 10, 1999
85 days to decisionK984266 · Product code: **MGQ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k984266/>**SUBMISSION DETAILS**

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|-----------------------|---|
| 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

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k984266/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 4, 2026