

**K933817 ROYL-DERM WOUND HYDROGEL STERILE UNIT
DOSE**Jan 10, 1994
159 days to decisionK933817 · Product code: **MGQ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k933817/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound And Burn, Hydrogel W/drug And/or Biologic (MGQ)
Date received	Aug 4, 1993
Decision date	Jan 10, 1994
Days to decision	159 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Renaissance Medical, Inc.
Location	Dana Point, CA, US
Contact	DARLENE TAYLOR-MCCORD
510(k) history	4 submissions · 4 cleared · 1992-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k933817/>; 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 6, 2026