

**K984370 HYPERGEL 20% HYPERTONIC SALINE GEL**Mar 1, 1999  
84 days to decisionK984370 · Product code: **MGQ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k984370/>**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	Dec 7, 1998
Decision date	Mar 1, 1999
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Molnlycke Health Care, Inc.</b>
Location	Eddystone, PA, US
Contact	MIGUEL A NEGRON
510(k) history	10 submissions · 9 cleared · 1998-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k984370/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026