

**K001148 MEROGEL OTOLOGIC PACK**Jun 3, 2000  
54 days to decisionK001148 · Product code: **KHJ** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k001148/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer, Ent Synthetic-polyamide (mesh Or Foil Material) (KHJ)
Date received	Apr 10, 2000
Decision date	Jun 3, 2000
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Xomed, Inc.</b>
Location	Arnold, MO, US
Contact	DAVE TIMLIN
510(k) history	82 submissions · 81 cleared · 1976-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k001148/> 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 May 21, 2026