

**K982294 XOMED SILICONE PRE-FORM BLOCKS**Sep 18, 1998  
80 days to decisionK982294 · Product code: **KHJ** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k982294/>**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	Jun 30, 1998
Decision date	Sep 18, 1998
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Xomed, Inc.</b>
Location	Arnold, MO, US
Contact	ROY BERENS
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/k982294/> 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