

**K981088 MILLS COLUMELLA PROSTHESIS**Jun 5, 1998  
72 days to decisionK981088 · Product code: **ETA** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k981088/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Replacement, Ossicular Prosthesis, Total (ETA)
Date received	Mar 25, 1998
Decision date	Jun 5, 1998
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Exmoor Plastics , Ltd.</b>
Location	Walker, MI, US
Contact	MARGARET BLACKEMORE
510(k) history	43 submissions · 43 cleared · 1981-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k981088/> 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 27, 2026