

**K944413 ACM PTFE SURGICAL MESH**Nov 9, 1994  
62 days to decisionK944413 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k944413/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Sep 8, 1994
Decision date	Nov 9, 1994
Days to decision	62 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>American Custom Medical, Inc.</b>
Location	Lubbock, TX, US
Contact	BRUCE G RUEFER
510(k) history	5 submissions · 5 cleared · 1994-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k944413/> 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 July 3, 2026