

**K111946 TEPHAFLEX MESH**Sep 26, 2011  
80 days to decisionK111946 · Product code: **OOD** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k111946/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgical Film (OOD)
Date received	Jul 8, 2011
Decision date	Sep 26, 2011
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tepha, Inc.</b>
Location	Cambridge, MA, US
Contact	MARY P LEGRAW
510(k) history	18 submissions · 17 cleared · 2007-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111946/> 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 26, 2026