

**K111337 TORNIER COLLAGEN COATED BIOFIBER SCAFFOLD**Jan 25, 2012  
258 days to decisionK111337 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k111337/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	May 12, 2011
Decision date	Jan 25, 2012
Days to decision	258 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tornier, Inc.</b>
Location	Beverly, MA, US
Contact	HOWARD L SCHRAYER
510(k) history	51 submissions · 51 cleared · 2000-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111337/> 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 June 15, 2026