

**K031188 ORTHOMEND**Jun 27, 2003  
73 days to decisionK031188 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k031188/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Apr 15, 2003
Decision date	Jun 27, 2003
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tei Biosciences, Inc.</b>
Location	Boston, MA, US
Contact	KENNETH JAMES
510(k) history	16 submissions · 16 cleared · 2002-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031188/> 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 1, 2026