

**K131286 PRIMATRIX DERMAL REPAIR SCAFFOLD**Aug 5, 2013  
91 days to decisionK131286 · Product code: **KGN** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k131286/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	May 6, 2013
Decision date	Aug 5, 2013
Days to decision	91 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/k131286/> 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