

**K061407 PRIMATRIX DERMAL REPAIR SCAFFOLD**Jun 29, 2006  
38 days to decisionK061407 · Product code: **KGN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k061407/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	May 22, 2006
Decision date	Jun 29, 2006
Days to decision	38 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061407/> 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