

**K970561 GRAFT PATCH**Aug 1, 1997  
169 days to decisionK970561 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k970561/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Feb 13, 1997
Decision date	Aug 1, 1997
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Organogenesis, Inc.</b>
Location	Canton, MA, US
Contact	DIANE E MINEAR, RAC
510(k) history	12 submissions · 12 cleared · 1997-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970561/> 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 27, 2026