

**K162922 GalaFORM 3D**Feb 23, 2017  
128 days to decisionK162922 · Product code: **OOD** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k162922/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgical Film (OOD)
Date received	Oct 18, 2016
Decision date	Feb 23, 2017
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Tepha, Inc.</b>
Location	Cambridge, MA, US
Contact	CONNIE H GARRISON
510(k) history	18 submissions · 17 cleared · 2007-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162922/> 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 26, 2026