

**K233999 GalaFLEX LITE Scaffold**Apr 9, 2024  
113 days to decisionK233999 · Product code: **OOD** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k233999/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgical Film (OOD)
Date received	Dec 18, 2023
Decision date	Apr 9, 2024
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233999/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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