

K161092 GalaSHAPE 3DAug 23, 2016
127 days to decisionK161092 · Product code: **OOD** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k161092/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgical Film (OOD)
Date received	Apr 18, 2016
Decision date	Aug 23, 2016
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tepha, Inc.
Location	Cambridge, MA, US
Contact	Connie H Garrison
510(k) history	18 submissions · 17 cleared · 2007-2024

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