

K180152 gel-e FlexJun 22, 2018
154 days to decisionK180152 · Product code: **QSY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k180152/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Wound Dressing Without Thrombin Or Other Biologics (QSY)
Date received	Jan 19, 2018
Decision date	Jun 22, 2018
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gel-E, Inc.
Location	College Park, MD, US
Contact	Elsa Abruzzo
510(k) history	3 submissions · 3 cleared · 2018-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180152/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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