

**K182811 gel-e Flex+**Aug 29, 2019  
330 days to decisionK182811 · Product code: **QSY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k182811/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Wound Dressing Without Thrombin Or Other Biologics (QSY)
Date received	Oct 3, 2018
Decision date	Aug 29, 2019
Days to decision	330 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182811/> 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 June 30, 2026