

K192667 gel-e Flex+ gel OTCOct 25, 2019
30 days to decisionK192667 · Product code: **QSY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192667/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hemostatic Wound Dressing Without Thrombin Or Other Biologics (QSY)
Date received	Sep 25, 2019
Decision date	Oct 25, 2019
Days to decision	30 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

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