

**K253609 TRAUMAGEL® 2.0 Hemostatic Gel**Dec 12, 2025  
24 days to decisionK253609 · Product code: **QSY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253609/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hemostatic Wound Dressing Without Thrombin Or Other Biologics (QSY)
Date received	Nov 18, 2025
Decision date	Dec 12, 2025
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cresilon, Inc.</b>
Location	Brooklyn, NY, US
Contact	Hassaan Ahmad
510(k) history	3 submissions · 3 cleared · 2023-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253609/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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