

K250319 MFUSE (MS001)Dec 15, 2025
314 days to decisionK250319 · Product code: **QSY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250319/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Wound Dressing Without Thrombin Or Other Biologics (QSY)
Date received	Feb 4, 2025
Decision date	Dec 15, 2025
Days to decision	314 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Machina Medical, Inc.
Location	Roswell, GA, US
Contact	Tiffini Wittwer
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250319/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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