

K253924 PuraStatJan 7, 2026
30 days to decisionK253924 · Product code: **QAU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253924/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hemostatic Device For Endoscopic Gastrointestinal Use (QAU)
Date received	Dec 8, 2025
Decision date	Jan 7, 2026
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	3-D Matrix Europe SAS
Location	Caluire Et Cuire, FR
Contact	Audrey Vion
510(k) history	4 submissions · 4 cleared · 2024-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253924/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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