

**K242250 PuraStat**Oct 22, 2024  
83 days to decisionK242250 · Product code: **QAU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k242250/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Device For Endoscopic Gastrointestinal Use (QAU)
Date received	Jul 31, 2024
Decision date	Oct 22, 2024
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242250/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026