FDA 510(k) Premarket Notification

K253924 PuraStat

CLEARED

Jan 7, 2026
30 days to decision

K253924 · Product code: **QAU** · General & Plastic Surgery
Source: 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