

K253290 XSTAT P15Nov 12, 2025
44 days to decisionK253290 · Product code: **PGZ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253290/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-absorbable, Expandable, Hemostatic Sponge For Temporary Internal Use (PGZ)
Date received	Sep 29, 2025
Decision date	Nov 12, 2025
Days to decision	44 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Revmedx, Inc.
Location	Washington, DC, US
Contact	Amy K. Pointer
510(k) history	7 submissions · 6 cleared · 2014-2025

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