

K170334 XSTAT 30, 3-PackMay 1, 2017
88 days to decisionK170334 · Product code: **PGZ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k170334/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-absorbable, Expandable, Hemostatic Sponge For Temporary Internal Use (PGZ)
Date received	Feb 2, 2017
Decision date	May 1, 2017
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary
Other names	XSTAT 30, 1-Pack; XSTAT 12, 3 Pack; XSTAT 12, 1 Pack

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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