

K210676 XSTAT 30 PouchAug 27, 2021
175 days to decisionK210676 · Product code: **PGZ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k210676/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-absorbable, Expandable, Hemostatic Sponge For Temporary Internal Use (PGZ)
Date received	Mar 5, 2021
Decision date	Aug 27, 2021
Days to decision	175 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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