

K161020 XSTAT-12, 3-Pack, XSTAT-12, 1-PackJul 28, 2016
107 days to decisionK161020 · Product code: **PGZ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k161020/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-absorbable, Expandable, Hemostatic Sponge For Temporary Internal Use (PGZ)
Date received	Apr 12, 2016
Decision date	Jul 28, 2016
Days to decision	107 days
Third-party review	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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161020/> 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 26, 2026