

K252282 SurgiCount+ SystemMar 16, 2026
237 days to decisionK252282 · Product code: **PBZ** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k252282/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Image Processing Device For Estimation Of External Blood Loss (PBZ)
Date received	Jul 22, 2025
Decision date	Mar 16, 2026
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Instruments
Location	Kalamazoo, MI, US
Contact	Michael Mazelin
510(k) history	72 submissions · 72 cleared · 1994-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252282/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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