

K243482 Self-Forming Magnet (Flexagon)Jun 11, 2025
215 days to decisionK243482 · Product code: **SAH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k243482/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Magnetic Compression Anastomosis System (SAH)
Date received	Nov 8, 2024
Decision date	Jun 11, 2025
Days to decision	215 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	GI Windows, Inc.
Location	Westwood, MA, US
Contact	Yverre Bobay
510(k) history	4 submissions · 4 cleared · 2025-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243482/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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